IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

Case No. 1:18-op-45749-DAP

THE BLACKFEET TRIBE OF THE BLACKFEET INDIAN RESERVATION,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG CORPORATION, et al.

Defendants.

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

PLAINTIFF'S OMNIBUS OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

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INTRODUCTION

The opioid epidemic has engulfed Plaintiff the Blackfeet Tribe of the Blackfeet Indian Reservation (the "Tribe" or "Plaintiff") in an unfolding tragedy with no foreseeable endpoint. In 2014, Native Americans experienced the highest prescription opioid overdose death rate of any racial or ethnic group. *Blackfeet Tribe* First Amended Complaint (ECF No. 6, under seal) ("FAC" or "Complaint") at ¶ 684. One Blackfeet Tribe tribal leader has described the epidemic as a "modern-day small pox." *Id.* at ¶ 688. "We had no time to resolve our grief then, and we are again enduring unresolved grief as we lose our people to these substances. We have no chance to heal." *Id.*

The public health crisis has overwhelmed the Tribe's resources. According to Tribal Health Department statistics, over half of newborn infants are born with an addiction condition, and this statistic has risen at an alarming rate. *Id.* at ¶ 686. The Tribe lacks the necessary resources for treatment, and the few options that are available are geographically isolated. *Id.* at ¶¶ 691-92. Despite extremely high rates of opioid use among pregnant women on the Reservation, only two inpatient treatment centers in the State of Montana regularly admit pregnant women, and they are located four or six hours away. *Id.* at ¶ 691. There is no medical detox facility on the reservation, and the Tribe does not have the resources to build or staff one. *Id.* at ¶¶ 692-93. Yet, when the Tribe instituted a needle exchange program, 5,500 needles were dispensed in the first year alone. *Id.* at ¶ 687.

Defendants admit that the Court is addressing a "nationwide crisis," while denying that they may be held accountable for it. *See* Mem. of Law in Support of the Manufacturer Defendants' Joint Motion to Dismiss the Tribes' Amended Complaints,

ECF No. 27-1 at 1 ("Mfr. Mem."); *see also* Mem. of Law in Support of Generic Manufacturers' Motion to Dismiss Plaintiff's First Amended Complaint, ECF No. 26-1 at 1 ("Gen. Mem.") ("opioid crisis"). But the worst public health emergency in modern times was not caused by any natural disaster, act of war, or a biological plague. Rather, it was orchestrated by the pharmaceutical industry for profit. Marketing Defendants relentlessly misrepresented the safety of opioid prescription drugs, convincing the medical community and the public that opioids were safe—essentially, that high doses of pharmaceutical-grade heroin could treat run-of-the mill pain without significant risk of addiction. The Marketing Defendants succeeded in the ubiquitous dissemination of misinformation, thereby preventing doctors and their patients from making informed treatment decisions. These Defendants converted a confined, niche market into a massive profit-making enterprise. Without their orchestrated machinations to cause skyrocketing opioid prescriptions, the opioid epidemic would not have occurred, and would not have become the crisis it is today.

After the market for dangerously addictive drugs was inflated, all of the Defendants flooded it, supplying opioids in quantities that they knew or should have known exceeded any legitimate market need, and failing to carry out their affirmative obligations to guard against diversion of these powerful narcotics. Marketing, Distributor, and National Retail Pharmacy Defendants[1] alike disregarded their legal obligations to

[1] The Complaint defines "Marketing Defendants" (the Actavis, Cephalon, Endo, Insys, Janssen, Mallinckrodt, and Purdue defendants) and "Distributor Defendants" (AmerisourceBergen, Cardinal, McKesson, Advantage Logistics, Albertson's, ANDA, Associated Pharmacies, Dakota Drug, Smith's, CVS, Walgreens, and Walmart.) (Although included in the Complaint in the definition of "Distributors," the latter three are separately broken out for some purposes in that document as "National Retail Pharmacies"). FAC ¶¶ 37-96. The defendants have divided themselves somewhat differently for purposes of their motions. A subset of the Marketing Defendants, consisting of Watson Laboratories, Inc., Actavis Pharma, Inc., Actavis LLC, Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., and for some purposes, Mallinckrodt LLC, SpecGx LLC, and Teva Pharmaceuticals USA, Inc., have moved as the

maintain effective controls against diversion, to report suspicious orders and prescribers, and to cut off drug supplies to illegitimate channels. They facilitated black markets for diverted prescription opioids and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—the prescription drugs.

Yet, according to Defendants, they bear no responsibility for the devastating effects of the dangerous drugs they marketed and distributed. Defendants seek to dismiss the Tribe's claims on a variety of grounds, the vast majority identical to the arguments made in motions to dismiss other complaints in this MDL. Aside from minor additions and variations to prior arguments, the motions in this case differ from the prior motions in three respects: (1) Defendants make arguments about standing and preemption that relate specifically to the Tribe's status as a sovereign Indian nation; (2) Defendants' arguments addressed to the Tribe's state-law claims implicate the law of Montana, which has not previously been briefed to this Court in this MDL; and (3) Generic Manufacturers have, for the first time, filed their own motion raising grounds for dismissal they believe are distinct as to them. In this opposition, the Tribe responds in detail in these three areas, while responding more summarily with respect to issues previously briefed and, wherever possible, cross-referencing the prior briefing of other MDL plaintiffs to avoid

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"Generic Manufacturers." The remainder of the Marketing Defendants, plus Mallinckrodt LLC, SpecGx LLC, and Teva Pharmaceuticals USA, have separately moved as "Manufacturer Defendants." CVS, Walgreens, and Walmart have filed a separate motion in which they refer to themselves as "Moving Defendants." In this brief, the terms "Marketing Defendants" and "National Retail Pharmacies" have the meanings defined in the Complaint (as do the separately-defined terms "RICO Marketing Defendants," *see* FAC ¶ 766, and "RICO Supply-Chain Defendants," *see* FAC ¶ 799). (For brevity, "National Retail Pharmacies" are sometimes referred to as "Pharmacies.") The terms "Manufacturer Defendants" (or "Manufacturers"), "Distributor Defendants" (or "Distributors"), and "Generic Manufacturer Defendants" (or "Generic Manufacturers") refer to the defendants who have so identified themselves in their motions; these terms are used primarily to identify which defendants have raised particular arguments.

duplication.[2] As discussed below, neither the Plaintiff's sovereign status nor the law of Montana provide any basis to dismiss the Tribe's claims. Nor do the issues raised by the Generic Manufacturers provide grounds to dismiss claims against those defendants. Thus, despite the new issues raised by the Defendants, the motion to dismiss the Tribe's claims should be denied in their entirety for the reasons set forth in prior briefing and below.

ARGUMENT

I. THE BLACKFEET TRIBE HAS STANDING AND ITS CLAIMS ARE NOT PREEMPTED

A. The Blackfeet Tribe Has Article III Standing to Bring this Lawsuit.

Only the Pharmacies argue the Blackfeet Tribe lacks Article III standing to bring this lawsuit, in one paragraph cross-referencing their *Summit County* briefing. This cursory standing argument is unavailing. First, under a standing analysis, a sovereign tribal nation like the Blackfeet Tribe is *not* the same as a political subdivision like Summit County. Like states, tribes retain sovereign powers that predate the formation of the United States and are recognized by federal law. The Tribe therefore has standing to assert its claims related to the well-being of the Tribe under its *parens patriae* authority. Second, the Tribe has separately satisfied the requirements for Article III standing to pursue its own proprietary losses.

Article III standing is established when a plaintiff alleges that it suffered an "injury in fact" that is "fairly traceable" to the defendant's conduct and "that is likely to be redressed by a favorable judicial decision." *Bank of America Corp. v. City of Miami,*

[2] Plaintiff refers primarily to the Omnibus Memorandum (Doc. # 654) filed by Plaintiffs County of Summit, Ohio, and City Of Akron, Ohio in opposition to the various motions to dismiss filed in that case, referred to herein as "*Summit* Opposition" or "*Summit* Opp. Mem.").

Fla., 137 S. Ct. 1296, 1302 (2017). An injury in fact is one that is concrete and particularized as well as actual or imminent. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice . . . ." *Id*. Finally, causation sufficient to satisfy Article III need not be proximate, nor need it be direct. *Lexmark Int'l, Inc. v. Static Control Components, Inc*., 572 U.S. 118, 134 n.6 (2014); *Parsons v. U.S. Dep't of Justice*, 801 F.3d 701, 713 (6th Cir. 2015); *see also United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 688 (1973) ("attenuated line of causation to the eventual injury" sufficient to establish standing) (parenthetically quoted in *Parsons*). The Tribe's allegations more than satisfy this standard.

1. The Blackfeet Tribe Has *Parens Patriae* Standing.

The Blackfeet Tribe of the Blackfeet Indian Reservation of Montana is a federally recognized tribe and has a formal nation-to-nation relationship with the United States government. Because of the Tribe's status as a sovereign tribal nation, it can assert claims in a *parens patriae* capacity.

The Supreme Court first recognized states' authority to bring *parens patriae* actions based on "quasi-sovereign" interests in *Louisiana v. Texas*, 176 U.S. 1, 19 (1900) (explaining that "the state of Louisiana presents herself in the attitude of parens patriae, trustee, guardian, or representative of all her citizens"). "Quasi-sovereign" interests, distinct from fully sovereign interests (such as the ability to make and enforce legal codes or to ensure the recognition of borders), and also distinct from a sovereign's own proprietary interests, "consist of a set of interests that the State has in the well-being of its populace." *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 602 (1982). These interests include, but are not limited to, the "health and well-being—both

physical and economic—of its residents." *Id.* at 607. In *Snapp*, the Supreme Court held that Puerto Rico is "similarly situated to a State" in that it had "a claim to represent its quasi-sovereign interests in federal court at least as strong as that of any State." *Id.* at 608 n.15.

Federally recognized tribes are also "similarly situated" to states in that they possess sovereign powers, but theirs necessarily predate those bestowed upon the states and even the formation of the United States itself. Tribal sovereignty is recognized by federal law, including by treaties, acts of Congress, executive branch policies and regulations, and federal court decisions. *See generally*, Nell Jessup Newton *et al*., eds., COHEN'S HANDBOOK OF FEDERAL INDIAN LAW (2005); Exec. Order No. 13175 § 3(a), 65 Fed. Reg. 67249, 67250 (Nov. 6, 2000) ("Agencies shall respect Indian tribal self-government and sovereignty, honor tribal treaty and other rights, and strive to meet the responsibilities that arise from the unique legal relationship between the Federal Government and Indian tribal governments."). Because of its sovereign status, a tribe, like a state, can invoke *parens patriae* standing when it "'allege[s] injury to a sufficiently substantial segment of its population,' 'articulate[s] an interest apart from the interests of particular private parties,' and 'express[es] a quasi-sovereign interest.'" *Table Bluff Reservation (Wiyot Tribe) v. Philip Morris, Inc.*, 256 F.3d 879, 885 (9th Cir. 2001) (citing *Snapp*, 458 U.S. at 607). And, as is true with states, "the health and safety of all its members is part of the Tribe's sovereign governmental interests." *Rosebud Sioux Tribe v. United States*, No. 3:16-cv-03038-RAL, 2017 WL 1214418, at *4 (D.S.D. Mar. 31, 2017) (internal citation omitted). Accordingly, numerous federal courts have implicitly or explicitly approved *parens patriae* standing for Native American tribes. *See, e.g.*, *Moe v.*

Confederated Salish & Kootenai Tribes of Flathead Reservation, 425 U.S. 463 (1976) (Indian tribe had standing as a tribe, apart from the claims of individual tribal members, to challenge state motor vehicle tax); *Delorme v. United States*, 354 F.3d 810, 816 (8th Cir. 2004) (noting tribe can have standing to sue to protect its own interests or, in appropriate situations, the interests of its members through a *parens patriae* action) (citation omitted); *Quapaw Tribe of Oklahoma v. Blue Tee Corp.*, 653 F. Supp. 2d 1166, 1179 (N.D. Okla. 2009) ("Indian tribes, like states and other governmental entities, have standing to sue to protect sovereign or quasi-sovereign interests").

The Tribe's Complaint sets forth the elements necessary to invoke *parens patriae* standing. First, the Tribe has articulated a quasi-sovereign interest in the health and physical and economic well-being of its tribal members that is separate and apart from the private interests of its members. *See, e.g.*, FAC ¶¶ 679, 681, 852 (alleging that the Defendants' misconduct has damaged the Blackfeet Nation by contributing to social ills such as violence, delinquency, child neglect, family dysfunction, opioid addiction, crime, poverty, property damage, damage to public spaces, decreased productivity, loss of tax revenue, and increased expenditures and diversion of the Blackfeet Nation's resources). The Tribe also alleges emotional harm to the Nation as a whole in the context of historical trauma. FAC ¶ 688. Second, the Tribe's allegations establish that Defendants' misconduct has affected all or substantially all of the Blackfeet Nation's members. *See, e.g.*, FAC ¶ 686 ("56% of Blackfeet Nation newborn infants are born with an addiction condition."); FAC ¶ 700 (alleging that Defendants' conduct "has hit the people of the Blackfeet Nation, approximately two thirds of whom live on the Blackfeet Reservation lands, hardest of all").

The Blackfeet Tribe has adequately pled a quasi-sovereign interest in the health and physical and economic well-being of a substantial majority of its members. This Court should recognize the Blackfeet Tribe's status as a sovereign nation as well as its authority to assert *parens patriae* standing under Article III.

2. The Blackfeet Tribe Also Has Article III Standing to Pursue Its Own Proprietary Losses.

The Blackfeet Tribe also has standing to assert claims of damages to its own proprietary interests. The Pharmacy Defendants argue that the harms alleged by the Blackfeet Nation here are non-justiciable generalized grievances, referring to their prior argument in the Moving Defendants' *Summit* Brief (ECF No. 497-1, at 4-7). Mem. in Supp. of MTD by CVS *et al.*, 1:18-op-45749-DAP (ECF No. 21-1) (hereinafter "Pharm. Mem.") at 3.[3] Pharmacy Defendants also assert that the Blackfeet Tribe has not sufficiently "set itself apart" from other injured parties or pleaded a direct injury to itself. *Id.*

The Tribe has adequately pled that Defendants' conduct has resulted in injury to the Tribe itself, not just individual members of the Blackfeet Nation. Defendants argue that the harms claimed by the Tribe "are at most the consequence of injury to others," Pharm. Mem. at 3, but even if that assertion captured all of the harms to the Tribe, that would not alter the fact that the Tribe itself has been injured as a result of Defendants' conduct in a concrete and particularized way and therefore has Article III standing to pursue its claims.

The Tribe has alleged that it has made, and will be required to make, direct payments from the public coffers to address the opioid crisis. The direct costs to the Tribe

[3] Plaintiff incorporates by reference the *Summit* Opp. Mem. at 106-109 (ECF No. 654).

include costs of "medication-assisted treatment, residential treatment, recovery housing, detoxification programs, and prevention efforts . . . as well as programs which provide education and naloxone to opioid users and family members." FAC ¶ 678. In addition, the Tribe alleged an increased volume in child abuse and neglect referrals, increased costs from drug-related crime, and increased costs from non-drug offenses, such as burglary, elder abuse, or domestic violence, that also are related to opioid use. FAC ¶¶ 679, 690. These specific tribal expenses more than satisfy Article III requirements, and Defendants' claims regarding "general grievances" should be rejected. *See Bank of America Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296, 1301-1304 (2017) (holding that government's allegations that unlawful racially discriminatory mortgage-lending practices impaired racial composition of the city, frustrated city's interests in integration and in promoting fair housing, and disproportionately caused foreclosures and vacancies in minority communities, decreasing property values, reducing property tax revenues and forcing City to spend more on municipal services sufficient to show that city was aggrieved and had standing); *Gladstone Realtors v. Vill. of Bellwood*, 441 U.S. 91, 110-11 (1979) (holding that village had standing to challenge discriminatory housing practices because "[a] significant reduction in property values directly injures a municipality by diminishing its tax base, thus threatening its ability to bear the costs of local government and to provide services").

Defendants conflate the two types of injury at issue here: the injury to tribal members' health and well-being, in which the Tribe has a quasi-sovereign interest, and the injury to the Tribe's own proprietary interests. The Tribe can bring claims based on both types of injury and does so in this lawsuit; that it has pled facts supporting both

claims brought in its *parens patriae* capacity and for its own damages does not convert the harm into a generalized grievance.

Pharmacy Defendants also assert that the Tribe's alleged harms are "indirect" and "cannot . . . be traced" to Pharmacy Defendants. Pharm. Mem. at 1. But as discussed below, the FAC sufficiently alleges that Plaintiff's injuries were caused by Defendants, including the Pharmacy Defendants. *See* discussion *infra* Section II.D.4. The FAC details Defendants' excessive distribution of narcotics into the sparsely populated geographic area that is home to the Blackfeet Nation. FAC ¶¶ 696-700. In pleadings that are sealed, the Tribe quantifies the volume of dangerously addictive drugs delivered into the Blackfeet Nation geographic area. *Id*. at ¶ 696. In sealed Paragraph 696, the Tribe provides examples of opioids shipped by certain pharmacies. *Id*. But even if this Court were to find proximate cause lacking with respect to any of Plaintiff's claims, Plaintiff would still meet the much lower traceability requirements for standing. *See Bank of Am. Corp*., 137 S. Ct. at 1302; *Lexmark*, 134 S. Ct. at 1391 n.6.

The Tribe has adequately pled injury, causation, and redressability under Article III, and Defendants' arguments to the contrary should be rejected.

B. The Tribe Has Standing to Recover Health-Related Costs.

The Manufacturer Defendants contend that the Tribe cannot recover two categories of healthcare expenses: (1) the costs of medical care directly provided by the Indian Health Service ("IHS"), and (2) medical costs funded under the Indian Self-Determination and Education Assistance Act, 25 U.S.C. §§ 5301 *et seq.* ("ISDEAA").[4] Mfr. Mem. at 19-23. Neither argument is correct.

[4] Although the Manufacturer Defendants' subheading for this argument section broadly states that "the Tribes cannot recover the costs of providing health care," Mfr. Mem. at 19 (cap. om.), Defendants'

1. The Tribe Seeks to Recover Its Own Healthcare Expenses, Not the Costs of IHS-Provided Care.

First, the Manufacturers argue that the Tribe lacks standing to recover healthcare expenses "[t]o the extent that the Tribes seek to recover the costs of medical care provided directly by IHS." Mfr. Mem. at 20. The simple answer is that the Tribe does *not* seek to recover the costs of medical care provided to its members directly by the IHS, but rather its own costs.[5]

Manufacturing Defendants rely on a single unpublished opinion, *Acoma Pueblo v. Am. Tobacco Co.*, in which the plaintiffs sought to recover from cigarette manufacturers an alleged $5.5 billion spent on Indian healthcare for tobacco-related illnesses since 1962. No. 99-CV-1049, slip op. (D. N.M. July 30, 2001), *filed at* Morris Decl. Ex. B, ECF No. 933-4, *and cited in* Mfr. Mem. at 20. In this opinion, which has never been cited by another court, the court concluded that federal statutes "rest[ed] the bottom line for Indian health care generally in the federal government and specifically in the Indian Health Service." *Id.* at 10. Regardless of the accuracy of that conclusion in 2001, it is inapplicable today, with IHS now operating only 17% of the healthcare facilities in the

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arguments involve only two categories of healthcare expenses. Defendants do not challenge the Tribe's right to recover for health-related expenses funded from non-IHS and non-ISDEAA sources, such as taxes, royalties, tribal government enterprises (including gaming revenues), grants, etc. Nor do they challenge the Tribe's right to recover non-healthcare expenses, such as increased costs for social services, courts, and law enforcement.

[5] The Indian Health Care System is not monolithic, and direct health care services by the IHS constitute a minority of it: of the 597 Indian health centers, clinics, and health stations, 83% are tribal-operated. *See* Indian Health Serv., *IHS Profile* (July 2018), https://www.ihs.gov/newsroom/factsheets/ihsprofile/ (calculated based on "Facilities" data listed on fact sheet). On the Blackfeet Indian Reservation, there are two small IHS facilities: Blackfeet Community Hospital in Browning, a 28-bed facility, and Heart Butte Health Station, a four-day-a-week clinic, in Heart Butte. The health-related costs to the Tribe are broader than the costs of direct medical care provided by IHS's two facilities. *See* FAC ¶¶ 686-93, 852, 883. For example, the Blackfeet Nation runs an addiction-treatment center in Browning that includes two beds for pregnant women—and greater capacity is desperately needed. *Id.* ¶ 691. In addition, the Tribe has also invested in efforts such as a needle-exchange program. *Id.* ¶ 687. Moreover, in order to abate the harms Defendants have caused, the Tribe seeks future costs of the services necessary to overcome the opioid epidemic, *Id.* ¶¶ 692-94, 966-973, 1124, which will necessarily fall to the Tribe due to the chronic underfunding of the IHS.

Indian Health Care System. Because the *Acoma* decision focuses on the costs of medical care provided *directly* by IHS, the case is inapposite here, where the Tribe is seeking to recover its own costs to stem the relentless spread of the opioid epidemic.

2. Defendants' Argument that MCRA Limits the Tribe's Recovery is Misplaced and Misunderstands the Law.

The Manufacturer Defendants' second argument – that the Tribe cannot recover medical costs funded under the ISDEAA because the Medical Care Recovery Act, 42 U.S.C. §§ 2651 *et seq.* ("MCRA") provides the Tribe no remedy – rests on a mischaracterization of Plaintiff's claims and a misreading of the relevant statutes. MCRA, which is incorporated into the Indian Health Care Improvement Act, 25 U.S.C. §§ 1601 *et seq.* ("IHCIA"), allows the Tribe to bring subrogation-types actions to recover certain medical expenses from third-party tortfeasors. But the remedies in MCRA are in addition to, not instead of, other available remedies. For that reason, the extent of the Tribe's subrogation rights under IHCIA and MCRA is not relevant here, where the Tribe is exercising its established right to recover damages that it, itself, has suffered as a result of Defendants' actions.[6] 25 U.S.C. § 1621e(k).

The Manufacturing Defendants mischaracterize the Tribe's claims through a convoluted statutory argument. Citing IHCIA, 25 U.S.C. § 1621e, Defendants assert that MCRA "governs" the Tribe's claims and leaves the Tribe "no remedy." Mfr. Mem. at 21.

[6] Tribes like the Blackfeet Nation, just as any sovereign, can bring suit to recover for the harms others cause them, including under tort theories. *See, e.g.*, *Quapaw Tribe of Oklahoma v. Blue Tee Corp.*, 653 F. Supp. 2d 1166, 1183 (N.D. Okla. 2009) (holding that the Quapaw Tribe has standing to assert common-law claims for natural resource damages on behalf of tribal members); *Havasupai Tribe of Havasupai Reservation v. Arizona Bd. of Regents*, 204 P.3d 1063, 1068-69 (Ariz. Ct. App. 2008) (tribe, on its own behalf and on behalf of its members, brought tort claims including fraud, misrepresentation, intentional infliction of emotional distress, negligence, gross negligence and negligence per se).

To understand why Defendants' arguments are misplaced, it is important to understand IHCIA and its relationship to MCRA.

Congress enacted IHCIA in 1976, authorizing appropriations and expanding health care service programs available through IHS, in recognition that "the unmet health needs of the American Indian people are severe and the health status of the Indians is far below that of the general population of the United States." Indian Health Care Improvement Act of 1976, Pub. L. No. 94-437, § 2(d), 90 Stat. 1400. At its inception, however, IHCIA did not give tribes the right to bring subrogation-like claims to recover medical expenses from health plans and responsible third parties. In 1992, Congress amended IHCIA to allow tribes the right of recovery in such cases. *See* Indian Health Amendments of 1992, Pub. L. No. 102-573, § 209, 105 Stat. 4526. In 2010, under the Patient Protection and Affordable Care Act, Congress expanded the tribal right of recovery further, explicitly adding "third-party tortfeasor" to the list of entities from whom tribes can recover. *See* Pub. L. No. 111-148, § 10221(a), 124 Stat. 119, 935 (2010) (enacting S. 1790, 111th Cong. § 125 (as reported by S. Comm. On Indian Affairs, Dec. 16, 2009)) (codified at 25 U.S.C. § 1621e(a)).

The 2010 amendments made clear that the tribal right of recovery in this subrogation-like context is the same as that provided to the federal government under MCRA, by explicitly incorporating MCRA by reference. 25 U.S.C. § 1621e(e)(3)(A). As a result, the 2010 amendments to IHCIA *expanded* tribal rights to recover through subrogated claims. Indeed, IHCIA contains a savings clause that expressly states that the statute does *not* limit a tribe's right of recovery under other laws:

> Nothing in this section shall be construed to limit any right of recovery available to the United States, an Indian tribe, or tribal organization under

> the provisions of any applicable, Federal, State, or tribal law, including medical lien laws.

25 U.S.C. § 1621e(k). Thus, nothing in IHCIA or MCRA limits a tribe to the new subrogation-like remedy in MCRA.

Here, MCRA is inapplicable because the Tribe is not asserting the subrogation-type claim created by the statute. The Tribe's action is not an aggregation of thousands of personal injury claims, with the Tribe merely the health insurer who paid the bills. On the contrary, the Tribe seeks to recover, in nuisance, negligence, and otherwise, for the opioid epidemic inflicted on its community.[7] Such costs are independent of whether any particular patient has or would have a right of action against Defendants or anyone else for any injuries.

Finally, to the extent the Manufacturing Defendants are contending that MCRA preempts the Tribe's common-law and statutory claims, this argument should be rejected. MCRA's express savings provision, quoted above, makes clear that Congress had no intention to preempt state law or to occupy the field with respect to health-care claims. MCRA does not preempt state law; on the contrary, the right to recovery under MCRA depends upon the viability of the underlying state-law tort claim.

[7] This is made clear by the scope of the remedy the Tribe seeks, which includes the cost of providing *future* healthcare services. Such future services are the Tribe's own damages and clearly do not, and could not, sound in subrogation. Similarly, the Tribe's costs for past healthcare services arise from the unprecedented scope of the epidemic and the extent to which the Tribe and its resources have been overwhelmed in trying to respond to it.

C. The Tribe's Claims Are Not Preempted by the Federal FDCA or by Any FDA Action.

1. The Tribe's Claims with Respect to Branded Drugs Are Not Preempted.

Manufacturer Defendants argue that the Tribe's claims are preempted by the federal Food, Drug, & Cosmetic Act ("FDCA") because their opioid products, and the labels for them, were approved by the Food & Drug Administration ("FDA"). *See* Mfr. Mem. at 42-48. This argument should be rejected for the reasons set forth in the *Summit* Opposition. *See Summit* Opp. Mem. at 114-22, §II.B.

In *Wyeth v. Levine*, the Supreme Court held that state-law claims involving FDA-approved drugs that would require the manufacturer to provide warnings different from or in addition to those approved by the FDA are not preempted where (as is generally the case for branded drugs) the manufacturer is permitted to make unilateral changes to the drug's approved label. 555 U.S. 555, 567-70 (2009). In *Levine*, the Supreme Court reiterated and applied its prior preemption jurisprudence, pursuant to which, in order to show that a claim is preempted by "conflict" or "impossibility" preemption, a defendant must show that it would have been impossible for it to comply with both state-law and federal law duties – that is, that federal law would have prohibited it from doing what the plaintiff says it ought to have done. *Id.* at 573; *see also PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) ("[S]tate and federal law conflict where it is impossible for a private party to comply with both state and federal requirements.") (citation and internal quotation marks omitted).

As explained in the *Summit* Opposition, Plaintiff's claims here are not preempted with respect to brand name drugs because (a) the Marketing Defendants are alleged to have made fraudulent misrepresentations, none of which had been approved by the FDA

or appeared in the labels for the drugs; and (b) as *Levine* makes clear, the Marketing Defendants were free, in any event, to make unilateral changes to their labels for their branded drugs.

Manufacturer Defendants here make an additional argument, not presented in the *Summit County* case, that Plaintiff's claims are preempted because FDA's rejection of a certain citizen's petition, known as the "PROP petition," shows that FDA would not have permitted Manufacturer Defendants to make unilateral changes to their labels in order to provide stronger warnings. In particular, they argue that FDA's denial of the petition shows that FDA would have rejected label changes with respect to the use of opioids for non-cancer chronic pain, as well as with respect to dosage and duration of treatment. For this reason, they contend it would have been impossible for them to provide the information Plaintiff says they ought to have provided. This argument is without merit.

FDA's denial of the PROP petition does not establish that the Manufacturer Defendants could not comply with their state-law duties for two reasons. First, with respect to the use of opioids for chronic pain, contrary to Manufacturer Defendants' argument, Plaintiff's claims do not turn on the contention that these Defendants should not have marketed their opioids products for non-cancer chronic pain. Rather, as described above, Plaintiff alleges that Manufacturer Defendants were precluded from using falsehoods and misrepresentations in such marketing. Each of these falsehoods is described in detail in the Complaint, which clearly demonstrates that the gravamen of Plaintiff's claim is not the promotion of opioids for non-cancer long-term use, but rather promotion for that use (and others) through fraudulent misrepresentations. *See, e.g.*, FAC ¶¶ 150, 202, 210, 225, 237, 254 (describing misrepresentations about the risks and

benefits of using opioids generally and specifically for chronic pain). No label change was required for the Manufacturer Defendants to stop using these fraudulent misrepresentations in connection with marketing opioids for their approved uses, including for chronic pain. For this reason, FDA's decision not to distinguish between cancer and non-cancer chronic pain has nothing to do with the claims asserted here. *See In re Opioid Litigation*, No. 400000/2017, 2018 WL 3115102, at *9 (N.Y. Sup. Ct. June 18, 2018) (holding that allegations of plaintiff governmental entities in opioid litigations were "not based upon the same theories and scientific evidence presented in the PROP petition").

More broadly, the arguments about the PROP petition lack merit because the denial of that petition does not establish that it was impossible for defendants to comply with both state and federal law. As already noted, branded drug manufacturers are not generally precluded from making unilateral changes to their labels. *See Levine*, 555 U.S. at 569-70. On the contrary, FDA regulations specifically allow for such changes, including changes to marketing materials (which Defendants take great pains to point out are part of a drug's "label"). *Id.*[8] A drug manufacturer may nonetheless argue that the FDA would have prohibited a particular change, but the manufacturer bears a heavy burden in doing so. It must come forward with "clear evidence" based on the administrative record that if it had updated its label pursuant to its duties under state law, FDA would have intervened and rejected the label change. *See Levine*, 555 U.S. at 571;

[8] For this reason, the Manufacturers' citations to *Strayhorn v. Wyeth Pharmaceuticals, Inc.*, 737 F.3d 378, 391 (6th Cir. 2013), and to *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 479 (4th Cir. 2014), both of which address impossibility preemption in the context of *generic* manufacturers, are inapposite here. (For the reasons discussed below, *Strayhorn* is also distinguishable and inapposite with respect to Plaintiff's claims against the Generic Manufacturers. *Drager*, which involved a contention that the generic manufacturer should have changed its label, is so far inapposite that, unlike the branded Manufacturers, the Generic Manufacturers do not even cite it.)

see also In re Fosamax (Alendronate Sodium) Prods. Liab. Litig., 852 F.3d 268, 285-86 (3d Cir. 2017) (holding that manufacturer must show by clear and convincing evidence that FDA would have rejected warnings plaintiff claims were necessary), *cert. granted sub nom. Merck Sharp & Dohme Corp v. Albrecht*, 138 S. Ct. 2705 (2018); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387 (7th Cir. 2010) (requiring evidence more persuasive than was available in *Levine*); *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1099 (10th Cir. 2017) (considering whether manufacturer presented clear evidence that FDA would have disapproved of the warnings suggested by plaintiffs and whether a reasonable juror could conclude that FDA would have approved those warnings).

This issue, however, presents a factual question that cannot be resolved at the pleading stage. *See Doe v. Miami Univ.*, 882 F.3d 579, 588 (6th Cir. 2018) (holding that on a motion to dismiss, a court "must construe the complaint in the light most favorable to the plaintiff and accept all allegations as true"). Although the Federal Circuit Courts of Appeals are split as to whether the question of what FDA would have done or did do with respect to proposed changes following approval of a drug presents a pure question of fact for a jury or a mixed question of law and fact for the court, *see Fosamax*, 852 F.3d at 293 (summary judgment not appropriate on issue of impossibility preemption where there was a disputed issue of fact as to whether FDA would have rejected the warnings plaintiffs contended were required under state law; issue was for the jury); *Mason*, 596 F.3d at 396 (based on administrative record, finding plaintiffs' claims not preempted because defendant "did not meet its burden of demonstrating by clear evidence that FDA would have rejected a label change warning"); *Cerveny*, 855 F.3d at 1099 (noting the issue, but declining to resolve it because the record before it showed that facts were

undisputed), *all* of the authorities agree that the issue requires a fully-developed factual record of the type available only at the summary judgment stage or beyond, *see Levine*, 555 U.S. at 581 (affirming verdict after trial); *Cerveny*, 855 F.3d at 1099 (finding no disputed issue of fact, affirming, in part, grant of summary judgment); *Fosamax*, 852 F.3d at 302 (vacating grant of summary judgment); *Mason*, 596 F.3d at 395-96 (reversing grant of summary judgment). Indeed, both of the cases cited by Defendants specifically on this issue were decided on full records on motions for summary judgment. *See Rheinfrank v. Abbott Labs., Inc.*, 680 F. App'x 369, 386 (6th Cir. 2017) (affirming grant of summary judgment); *Cerveny*, 855 F.3d at 1099 (affirming, in part, grant of summary judgment).

This is especially true because numerous cases have, in the end, rejected claims of impossibility specifically in the face of FDA's denial of citizens' petitions seeking similar label changes. *See Mason*, 596 F.3d at 394-95 (finding "FDA's rejection of the citizen petitions or its call to do more research" insufficient to show by clear evidence that FDA would have rejected proposed changes); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 1836435, at *9-11 (N.D. Ill. May 8, 2017) (finding rejection of citizens' petition insufficient to demonstrate that FDA would have rejected different label); *Hunt v. McNeil Consumer Healthcare*, 6 F. Supp. 3d 694, 700-01 (E.D. La. 2014) (same); *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142, 1157-60 (C.D. Cal. 2010) (same). In none of these cases did the court find denial of a citizens' petition sufficient evidence to show what FDA would have done, based on detailed factual background placing those events in context. Rather, in each case, the court found that upon examination of the full record, including the specific

phrasing of the citizens' petition and the specific nature and basis of FDA's rejection of the petition, the manufacturer had failed to carry its burden to show that the change at issue in the case would have been rejected. Of greatest significance here, in the governmental opioids litigation in New York, where Defendants offered the same argument based on the very same PROP petition at issue here, the court specifically found that, at the pleading stage, "the FDA's 'less-than-definitive determination' concerning PROP'S request for maximum dosage and treatment duration does not meet the *Wyeth* standard of clear evidence." *See In re Opioid Litigation*, 2018 WL 3115102, at *9.

This Court should reach the same conclusion. Without a factual record and without discovery, the Court cannot determine precisely what the FDA considered and rejected in connection with the PROP petition. And because rejection of a citizens' petition is not necessarily sufficient, even at the summary judgment stage, to show that FDA would have prevented a manufacturer from making a particular change to its label, let alone a change to its marketing representations, it is all the less sufficient to make that showing *by clear evidence* on a motion to dismiss.

2. The Tribe's Claims Involving Generic Drugs Are Not Preempted.

The Generic Manufacturers' contention that the Tribe's fraud- and marketing-based claims are preempted as to them because of the separate regulatory obligations of generic manufacturers should also be rejected. As do the brand-name Manufacturer Defendants, the Generic Manufacturers assert implied "conflict" or "impossibility" preemption, pursuant to which state laws that conflict with federal law are preempted. Gen. Mem. at 9-13. But, even under the different regulatory scheme for generic drugs,

the Generic Manufacturers cannot show that the state-law duties that give rise to Plaintiff's claims conflict with any federal statutory or regulatory duties, or that it was impossible for them to comply with both. No federal law or regulation required the Generic Manufacturers to make false and fraudulent misrepresentations that had not been approved by the FDA and did not appear in the approved drug labels.[9] Nor did any federal law or regulation prevent the Generic Manufacturers from affirmatively providing doctors and patients with adequate and truthful warnings that did not differ in content from the approved warnings in the labels, as Plaintiff alleges they ought to have done.

The Generic Manufacturers rely on *Mensing*, where the Court found that failure-to-warn claims requiring warnings in a generic drug label different from those contained in the branded label are preempted because, under the applicable regulatory scheme, generic manufacturers (unlike brand-name manufacturers) are not permitted to make unilateral changes to the label. Instead, manufacturers of generic drugs are required to maintain a label identical to that of the branded equivalent. 564 U.S. at 613-14. Because generic manufacturers are specifically prohibited from changing the approved labels, it would be impossible for them to comply with state-law obligations that require such changes. For that reason, a manufacturer of a branded drug may be held liable for failing to add a needed warning to its label, but the manufacturers of the corresponding generic drug, who are not permitted to make such changes, may not be.

The Generic Manufacturers rest their argument on the "duty of sameness" recognized in *Mensing*, arguing that because they were precluded from changing their labels for their opioid drugs, it would have been impossible for them to comply with the

[9] The Generic Manufacturers do not argue that claims relating to fraudulent misrepresentations are preempted, but deny that they made any such misrepresentations. As discussed below, for purposes of this motion, Plaintiff's allegations that they did must be accepted as true.

duties Plaintiff seeks to impose on them here.[10] But *Mensing* is of no use to the Generic Manufacturers because *Plaintiff's claims do not rest on the contention that these defendants ought to have changed their labels or to have marketed their drugs with any statements in conflict with their approved labels.* And the Sixth Circuit has already held that only failure-to-warn claims that would require different or additional warnings are preempted under *Mensing*. *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 583-85 (6th Cir. 2013).

In *Fulgenzi*, the plaintiff alleged that the defendant generic drug manufacturer failed to provide an adequate warning when it failed to update its label to include information that had been added to the label for the brand-name equivalent. 711 F.3d at 581-82. The defendant argued (and the district court held) that the claims were preempted under *Mensing* on the theory that all claims that sound in failure-to-warn are preempted to the extent asserted against manufacturers of generic drugs. *See Fulgenzi v. PLIVA, Inc.*, 867 F. Supp. 2d 966, 971 (N.D. Ohio 2012), *rev'd*, 711 F.3d 578 (6th Cir. 2013). The Sixth Circuit reversed. In doing so, the Court held that, under *Levine* and *Mensing*, "the key question is 'whether the private party could independently' comply with its state duty." *Fulgenzi*, 711 F.3d at 584 (quoting *Mensing*, 564 U.S. at 620). Looking at the specific facts of the case before it, the Sixth Circuit found that, in *Fulgenzi*, the defendant could have independently updated its labeling to match that of the branded manufacturer (and indeed had a duty to do so). *Id.* Because it was not impossible for the defendant to comply with both its state-law duties to warn and its

[10] The Generic Manufacturers also rely on *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), but *Bartlett* adds little, if anything, to the analysis here. In *Bartlett*, the Supreme Court held that a manufacturer precluded from altering the label for a generic drug to add an adequate warning could not be required by state law to stop selling the product altogether. *Id.* at 488-90. Plaintiff here does not allege that the Generic Manufacturers should have stopped selling their products.

federal duty of sameness, the claim was not preempted. Under *Fulgenzi*, the court cannot simply assume that claims against generic manufacturers that involve warnings are preempted. Rather, the court must analyze the particular facts of the case to determine whether compliance with both federal and state law is impossible.

When Plaintiff's claims against the Generic Manufacturers are analyzed as required under *Fulgenzi*, it is clear they are not preempted. As pertinent here, Plaintiff contends that the Generic Manufacturers were obliged to correct or counter the serious and pervasive misrepresentations in the market through "Dear Doctor" letters or other forms of communication with doctors. The Generic Manufacturers argue that they are precluded from sending such letters because all such communications are considered to be part of a drug's label. This argument is beside the point because the corrective disclosures at issue here *need not have conflicted with or differed in content from any information on the FDA-approved label for any opioid.*

This is so because the Marketing Defendants' fraudulent promotion neutralized the warnings on the label without appearing to contradict them. The labels said these drugs are addictive. The Marketing Defendants' promotion said: but not if you are taking them for pain. *See* FAC ¶ 150 ("Through their marketing efforts, the Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by 'legitimate' pain patients."). The defendants' marketing campaign told doctors and patients that the addiction warnings on the labels didn't apply to them if they were genuinely taking the drugs for pain. But, as alleged in the Complaint, this was false. There was no research then, or now, that supports the idea that patients taking opioids for pain can't or won't get addicted. *Id.* at ¶ 152. And by convincing doctors that addiction

was only a risk for drug-seekers, for addicts, for people who already had substance abuse problems, thus nullifying the warning on the label, the Marketing Defendants persuaded them that the risk-benefit calculation would almost always come out in favor of using opioids.

In addition, Marketing Defendants over-stated the benefits of opioids for long-term use. *See* FAC. ¶¶ 225-236 (defendants falsely claimed that opioid doses could be increased without limits), ¶¶ 237-53 (defendants overstated the extent to which long-term opioid use improves functioning), ¶¶ 254-263 (defendants falsely claimed that opioids are safer than other therapies). Given the addiction risks, given the problems of tolerance, dependence, and sedation, especially with escalating doses, the truth was that opioids are only rarely the right choice for chronic pain. But doctors couldn't make that assessment, because the Marketing Defendants' advertising told them that these drugs had been shown to be "highly effective" for chronic use, and that these drugs were actually safer than non-opioid pain relievers.

None of this was true – *and none of it was on the label*, so the duty of "sameness" did not apply to these statements. The Generic Manufacturers – who have the same duty to warn about the dangers of their products as branded manufacturers do, so long as they are able to do without violating federal law – knew that the market had been saturated with falsehoods about opioids and that these falsehoods undermined the labels that were supposed to warn doctors about the true risks of these drugs. In order to safely and carefully market these dangerous products, the Generic Manufacturers were required, to the extent possible, to correct these dangerous falsehoods. Such correctives would not have needed to contradict or even supplement the label; instead, they would simply have

reinforced and reinstated the impact of the warnings that were already there. Nor would such correctives have implied a therapeutic difference between the branded and generic versions of the drugs because the correctives would merely have reiterated information that was already contained in the labels for both branded and generic opioids.

Unable to show that any particular corrective at issue in this case would have contradicted or been in addition to any statement on the label for the opioid products, Generic Manufacturers instead suggest that there is a blanket rule prohibiting manufacturers of generic drugs from making *any* "additional disclosures" (e.g., sending "Dear Doctor" letters) but this argument makes no sense. As these defendants themselves recognize, the only distinct limitations on generic manufacturers relate to their duties to maintain labels identical to those of the branded equivalent drug. Where, as here, Plaintiff's claims do not require warnings different from, or in addition to, the warnings on the labels, but rather call for reiteration and emphasis of the warnings already there, there can be no violation of the duty of sameness and thus no conflict between state and federal law. *See Fulgenzi*, 711 F.3d at 585-86; *Teva Pharmaceuticals USA, Inc. v. Superior Court*, 217 Cal. App. 4th 96, 114-15 (2013), *cert. denied*, 135 S. Ct. 1152 (2015).

Defendants' argument – that generic manufacturers are precluded from sending "Dear Doctor" letters, even when the letters provide information identical to that on the branded-drug label – was specifically rejected by the California Court of Appeals in *Teva v. Superior Court*, 217 Cal. App. 4th 96. There, the court held that federal regulations do *not* prohibit a generic drug manufacturer from sending out a "Dear Doctor" letter or other communication to doctors about its generic drug products, so long as the information in

the communication is also contained in the name-brand product label. *Id.* at 112-15. Citing the Sixth Circuit's *Fulgenzi* opinion, the *Teva* court looked at the specifics of what the plaintiff alleged the defendant should have done and determined that, at least with respect to providing information that was contained in the brand-name label, the plaintiff's claims were not preempted. *Id.* at 106-108.

This is also the position of the United States government (and, therefore, the FDA). At the invitation of the United States Supreme Court, the United States submitted an *amicus* brief with regard to Teva's petition for *certiorari* to the high Court with respect to the decision of the California Court of Appeals. In that *amicus* brief, the government set forth its view that federal drug regulations prohibit "Dear Doctor" letters and similar communications from generic manufacturers only to the extent that such communications include new or additional safety information not contained within the name-brand label. As set forth in the *amicus* brief, the *Mensing* decision goes no further and does not provide a blanket rule of preemption. *See* Brief for United States as *Amicus Curiae, Teva Pharmaceuticals USA, Inc. v. Superior Court of California, Orange County*, No. 13-956, 2014 WL 7169712, at *20-22 (Dec. 16, 2014). As urged by the United States, the Supreme Court denied the petition, and the decision of the California Court of Appeals on this issue stands. Because the *Teva* decision involved communications to health-care providers containing information that was on the brand-name label, it is on point here where the Generic Manufacturers failed to provide corrective disclosures reiterating warnings that were already on the brand-name label. Consistent with the holding of *Fulgenzi*, this Court should follow the California Court of

Appeals in *Teva* and the argument set forth by the United States in its *amicus* brief and reach the same conclusion.

The authorities cited by the Generic Defendants are not to the contrary. In *Strayhorn v. Wyeth Pharmaceuticals, Inc*., the plaintiffs argued that "the Generic Manufacturers, on their own initiative, could have distributed 'Dear Health Care Professional' or "Dear Doctor" letters to medical professionals *to warn them of the dangers of metoclopramide that were not adequately communicated on the drug's label*." 737 F.3d 378, 391 (6th Cir. 2013) (emphasis added). The court found the claim preempted under *Mensing* because letters such as the ones the *Strayhorn* plaintiff proposed would be different from the warnings in the labelling of the brand-name drug. The court had no occasion to consider a claim based on "Dear Doctor" letters that would contain *only* information already found in the label, nor did it have the benefit of the *amicus* brief filed in the *Teva* litigation one year later.

In re Darvocet, Darvon, and Propoxyphene Products Liability Litigation, 756 F.3d 917 (6th Cir. 2014), is no more helpful to the Generic Manufacturers. There, the plaintiff made only a "perfunctory" argument, in a footnote, that the defendants should have sent "Dear Doctor" letters or similar communications. *Id.* at 932. The Court held that the argument had been forfeited or waived by the plaintiffs' failure to develop it. *Id.* Moreover, the court grounded its ruling with respect to the "failure to communicate" claim on the "duty of sameness." *Id.* at 932-33. Because that duty is not violated here, *Darvocet* is inapplicable.

The Generic Manufacturers also rely on *McDaniel v. Upsher-Smith Laboratories, Inc.*, 893 F.3d 941, *reh'g en banc denied* (6th Cir. 2018), but this case is even more

inapplicable. In *McDaniel*, the plaintiff alleged the defendants had violated FDA regulations that required them to distribute a medication guide. *Id.* at 943. The plaintiff did not allege, and was unable to identify, any parallel state-law duty that would have required distribution of the guide. *Id.* The court held that the claim was preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), because only the FDA could sue to enforce the regulations. Here, by contrast, Plaintiff asserts state-law claims sounding in fraud and does not seek to enforce FDA regulations. *McDaniel*, 893 F.3d at 944. Nothing in *McDaniel* addresses the extent to which manufacturers of generic drugs may communicate with health-care providers without violating the duty of sameness with respect to the labelling of the drugs.[11]

II. DEFENDANTS' GENERAL DEFENSES SHOULD BE REJECTED

Defendants assert a series of generalized defenses they contend require dismissal of all of Plaintiff's claims. None of these defenses has merit.

A. Plaintiff's Claims Are Not Barred by the Statute of Limitations.

The Manufacturers argue that the Plaintiff's claims are barred by the statute of limitations. Mfr. Mem. at 58-66. Plaintiff incorporates Summit County's response on this issue. Summit Opp. Mem. at 122-128.

First, as a general matter, the Plaintiff is a sovereign authority and possesses the common law privilege of *nullum tempus* – which precludes the statute of limitations

[11] The Generic Manufacturers argue, in footnote 5 of their motion to dismiss the *Muscogee Nation* Complaint (adopted by reference in the Blackfeet Tribe's motion to dismiss at 1, 3-4), that Plaintiff's RICO Opioid Marketing Enterprise claim is precluded by analogy to federal preemption. Because, for the reasons stated in the text, there is no federal preemption here, there can be no analogous preclusion. But even if that were not so, a decision on whether a federal claim is precluded by the provisions of another federal statute requires a statutory analysis that may be informed by concepts of preemption. *Pom Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014). Here, the Generic Manufactures have not undertaken the statutory analysis required to assert an argument that the FDCA precludes a RICO claim.

defense from being raised by a defendant whose conduct is alleged to have injured the sovereign. *See Pequot Pharm. Network v. Connecticut Hospice, Inc.*, No. CV-GC-2015-104, 2015 WL 9601099, at *6-7 (Mash. Pequot Tribal Ct. Dec. 10, 2015) ("as a general matter, this Court holds that the Mashantucket Pequot Tribal Nation possesses the common law privilege of *nullum tempus*."); and *State ex rel. Condon v. City of Columbia*, 528 S.E.2d 408, 412 (S.C. 2000). This alone is sufficient to defeat the statute of limitations challenge.

Second, Plaintiff's FAC alleges an abatable continuing nuisance. Under Montana law the statute of limitations on equitable nuisance claims "is tolled until the source of the injury is abated." *Knight v. City of Missoula*, 827 P.2d 1270, 1277 (Mont. 1992); *see also Graveley Ranch v. Scherping*, 782 P.2d 371 (Mont. 1989). In this case, the nuisance has not been abated. Thus, the Plaintiff's equitable nuisance claims are not time-barred.

Third, the statute of limitations is an affirmative defense, such that dismissal at this stage is rarely appropriate. *See* Fed. R. Civ. P. 8(c)(1); *United States v. N. Trust Co.*, 372 F.3d 886, 888 (7th Cir. 2004) ("Dismissal under Rule 12(b)(6) was irregular, for the statute of limitations is an affirmative defense.") (citing Rule 8(c)). It is only when the "allegations in the complaint *affirmatively* show that the claim is time-barred" that dismissal under Rule 12(b)(6) is appropriate, *Cataldo v. US Steel Corp.*, 676 F.3d 542, 547 (6th Cir. 2012), especially when, as here, factual disputes exist as to the application of the discovery rule. *E.g.*, *Akkerman v. Mecta Corp.*, 72 F. App'x 652 (9th Cir. 2003) (reversing dismissal and reasoning that jury could find that the discovery rule tolled limitations).

As set forth below, the Tribe's allegations in the FAC do not affirmatively show that the "vast majority" of its claims are time-barred, even if what Manufacturers describe as "publicly available material" (FDA's regulatory actions, articles related to opioids and opioid addiction, marketing efforts regarding opioids, and previously filed Complaints pertaining to opioids) are considered.[12] In fact, none of the Tribe's claims are time-barred and Defendants' motion to dismiss should be denied.

1. The Discovery Rule Applies to Plaintiff's Claims.

Montana law controls when the statute of limitations begins to run. Montana Section 27-20-102(3) provides the basis for a version of the "discovery rule" through a tolling provision and sets forth that:

> The period of limitation does not begin on any claim or cause of action for an injury to person or property until the facts constituting the claim have been discovered or, in the exercise of due diligence, should have been discovered by the injured party if:
>
> (a) the facts constituting the claim are by their nature concealed or self-concealing; or
>
> (b) before, during, or after the act causing the injury, the defendant has taken action which prevents the injured party from discovering the injury or its cause.

Under Montana law, "[a]t what point [plaintiff] discovered or should have discovered through due diligence the negligence of [defendant]" is a question that must be submitted to a jury for determination. *McCormick v. Brevig*, 980 P.2d 603, 620 (Mont. 1999).

Plaintiff has sufficiently pleaded that the Marketing Defendants (as well as the other Defendants) have taken actions that prevented the Tribe from discovering the injury

[12] Moreover, dismissal is not appropriate to the extent that Defendants are seeking to use the statute of limitations to limit admissible evidence or claims periods with respect to a claim that is otherwise valid. *See Charles v. Front Royal Volunteer Fire & Rescue Dep't, Inc.*, 21 F. Supp. 3d 620, 629 (W.D. Va. 2014) (Rule 12(b)(6) motion "may be used only to dismiss a 'claim' in its entirety"); *Janis v. Nelson*, No. CR. 09-5019-KES, 2009 WL 4505935, at *7 (D.S.D. Nov. 24, 2009) (same).

or its cause. Plaintiff alleges the existence of a coordinated and concealed Opioid Marketing Enterprise, which included: (i) payment by manufacturers of rebates and/or chargebacks to the Distributor Defendants, (FAC ¶ 515) (ii) collaboration to ensure that the opioid production and procurement quotas set by the DEA remained high, (FAC ¶ 535); (iii) efforts to surreptitiously undermine policies and prescribing recommendations that limited opioid use, (FAC ¶¶ 773-775) and (iv) creation and distribution of a body of misleading medical literature, advertising, training materials, and CMEs and speaker presentations. FAC ¶ 779. The scheme alleged by Plaintiff could not have succeeded without the close collaboration of the Marketing Defendants, Distributor Defendants, Front Groups, and KOLs, and this close collaboration was concealed from Plaintiff and the public. FAC ¶ 768.

Furthermore, Plaintiff sufficiently alleges that the Marketing Defendants disseminated many of their misrepresentations through the guise of objective third parties, KOLs and Front Groups, while hiding the fact that the Marketing Defendants were funding them and controlling their messaging. FAC ¶ 320-363 (discussing Front Groups); FAC ¶ 364-398 (discussing KOLs). Marketing Defendants' role in directing the Front Groups was hidden from the public and intended to stay that way.[13]

Additionally, when some information about the dangers of opioids began to filter through these defendants' pervasive misrepresentations, the Marketing Defendants responded by (1) blaming a few "bad actor" physicians and patients, *see* FAC ¶ 560, and (2) claiming that their new, patent-protected formulations of opioid medication would deter abuse and resist tampering, *see* FAC ¶¶ 276-317.

[13] Indeed, one major front group, the American Pain Foundation, disbanded as soon as its financial ties to the Manufacturer Defendants became public. FAC ¶ 332.

Finally, Marketing Defendants (along with Distributor Defendants) also hid their lack of cooperation with law enforcement, while making public assurances that they were committed to working with public authorities to preventing diversion. FAC ¶ 580-585. Purdue, for example, asserted a need for secrecy about its supposed anti-diversion programs, stating that "[i]mproperly disclosing the workings of these programs is irresponsible and only aids those seeking to divert and abuse prescription opioids, potentially worsening a national health crisis." FAC ¶ 581. Based on all these allegations, Plaintiff alleges that it did not discover the nature and magnitude of Defendants' misconduct, nor could they have acquired such knowledge earlier through the exercise of reasonable diligence. FAC ¶ 726-727. No more is required at the pleading stage.

Indeed, under Montana's tolling statute, this issue should be submitted to the finder of fact to determine whether this information was of such a public nature that a reasonable person would have known, or by the exercise of reasonable diligence should have known, of the elements of a possible cause of action and at what point a reasonable person would have made such a discovery.

The Defendants cannot escape the application of the discovery rule in this case by reference to what they describe as publicly available material (FDA's regulatory actions, articles related to opioids and opioid addiction, and marketing efforts regarding opioids) contained within Plaintiff's Complaint. Manf. Mem. at 62-63. Nor can they escape the application of the discovery rule based on the *City of Chicago* and *Santa Clara* lawsuits.

Manf. Mem. at 64-66. The cases relied on by the Manufacturer Defendants are easily distinguishable.[14]

2. The Continuous Violations Doctrine Applies to Plaintiff's Claims.

As noted above, the statute of limitations is tolled with regard to Plaintiff's claim for equitable relief as a result of a continuing, abatable nuisance. Furthermore, the continuous violations doctrine extends the statute of limitations for Plaintiff's other claims. For instance, the conduct constituting civil RICO violations is likewise continuing. Plaintiff incorporates Summit County's response on the continuous violations doctrine. Summit Opp. Mem. at 126-28.

Montana has adopted the continuous tort theory for nuisance and negligence claims. *Christian v. Atlantic Richfield Co.*, 358 P.3d 131 (Mont. 2015). Montana courts have held that where a nuisance is of a continuing nature, a new cause of action accrues each time the nuisance causes damage and the statute of limitations period for the last possible cause of action begins to run from the date the nuisance is removed. *See*

[14] *Reaves v. Cable One, Inc.*, No. 1:11-cv-03859-MHH, 2015 WL 12747944, *3 (N.D. Ala. Mar. 16, 2015) is distinguishable as the class action cases involved in it were based on public disclosures to Congress in August 2008 that the defendant had violated the Electronic Communications Privacy Act ("ECPA") by installing spyware devices on its broadband networks and funneling subscribers' internet communications to a third-party advertisement service company. The action in question was commenced in 2011. The district court determined that it need not guess when a reasonably diligent plaintiff would have discovered the facts constituting Cable One's alleged ECPA violation because a group of plaintiffs had brought a class action in November 2008 based on the 2008 public disclosure of the violation. *In re Wells Fargo Mortg.-Backed Certificates Litig.*, No. 09-cv-013756-LHK, 2010 WL 4117477, at *1-2 (N.D. Cal. Oct. 19, 2010), is also distinguishable. Plaintiffs there conceded that their claims were barred unless the statute of limitations had been tolled, pursuant to *American Pipe & Construction Co. v. Utah*, 414 U.S. 538 (1974), by the filing of a prior class action. The court found that because the prior putative class plaintiff lacked standing to bring the claim, the prior action did not toll the statute for other class members. Plaintiffs' concession that their claims were barred absent *American Pipe* tolling makes the case completely inapplicable here. *Thieltges v. Royal Alliance Assocs., Inc.*, 334 P.3d 382, 384 (Mont. 2014) does not support the Manufacturer Defendants' contention that the Tribe could have readily discovered the relevant facts through public records regarding the *Chicago* and *Santa Clara* lawsuits. *Thieltges* merely held that a public records search of a named defendant, Peterson, whom the Complaint identified as a registered securities salesperson in Montana, would have disclosed that Peterson was registered as a salesperson with Royal Alliance, thus, no information was concealed with regard to Royal Alliance and the statute of limitations was not tolled as to any claims against Royal Alliance.

Graveley, 782 P.2d at 373; and *Shors v. Branch*, 720 P.2d 239 (Mont. 1986). Under Montana law, "if the injury is of a nature that may be considered continuing, the plaintiff may allege an appropriate theory of the defendant's liability for that injury." *Christian*, 358 P.3d at 150.

The continuing tortious and unlawful conduct by the Defendants has caused a repeated and continuous injury. The tort is not completed and the wrongdoing and unlawful activity by Defendants has not ceased. The damages have not occurred all at once but continue to occur and indeed have increased as time progresses. Plaintiff's Complaint alleges appropriate theories of liability associated with its ongoing and continuous injury such that the continuous violation doctrine applies to those claims and tolls the statute of limitations.

B. The Free Public Services Doctrine Does Not Bar Plaintiff's Claims.

The Manufacturer and Pharmacy Defendants contend that the Tribe cannot recover the costs of providing public services under the Free Public Services Doctrine. Defendants, however, cite to no Montana law in support of their position. Mfr. Mem. at 23-25; Pharm. Mem. at 19. Nor could they because Montana has not adopted the doctrine. Rather, Pharmacy Defendants merely cite to *City of Flagstaff v. Atchison, Topeka & Santa Fe Railway Co*., 719 F.2d 322, 323 (9th Cir. 1983), and the defense briefing filed in the Chicago Opioid litigation. In response, Plaintiff incorporates by reference the Chicago Opp. Mem. at 36-37 and the Cabell Opp. Mem. at 36-38, and notes that even if it were applicable in Montana, it would not bar the Tribe's claims. Courts have rejected the application of the doctrine in cases where the repeated course of conduct by the Defendants required the municipality to expend substantial governmental funds on a continuous basis. *See* Cabell Opp. Mem. at 38. Thus, the free public services

doctrine would, nevertheless, not apply to the extraordinary, unanticipated public costs associated with the opioid crisis which resulted from the Defendants' continuous course of conduct.

This Court should decline Defendants' invitation to create the municipal cost recovery rule in Montana, and then expand the rule to apply it in these circumstances. *See City of Everett v. Purdue Pharma L.P.*, No. C17-209RSM, 2017 WL 4236062, at *7 (W.D. Wash. Sept. 25, 2017) (declining to find the Free Public Services Doctrine applicable in similar circumstances against some of the same defendants based on the same course of conduct); *In re Opioid Litigation*, No. 400000/2017, 2018 WL 3115102, at *22 (N.Y. Sup. Ct. June 18, 2018) (same).

C. The Blackfeet Tribe Plausibly Alleges that Defendants Proximately Caused the Tribe's Injuries.

The Manufacturers argue that Plaintiff has failed to plead proximate cause for any of its claims, but ignore almost entirely the quite different standards applicable to proximate cause for a RICO claim and proximate cause for the remainder of the Tribe's claims. For their part, the Distributors purport to recognize that different standards apply, but treat the Montana-law standard applicable to Plaintiff's state-law claims only cursorily. Defendants' arguments fail in any event, because the Tribe has sufficiently pleaded that Defendants' conduct caused Plaintiff's injury under either the RICO standard or the Montana common law standard.[15]

[15] Applying the laws of their respective jurisdictions, other courts hearing governmental-plaintiff opioid cases have rejected Defendants' proximate cause argument. *See, e.g., State of New Hampshire v. Purdue Pharma L.P., et al.*, No. 217-2017-CV-402, Order (N.H. Sup. Ct. September 18, 2018) (filed as Exhibit 1 hereto); *Commonwealth of Ky. v. Endo Health Solutions, Inc. et al*., C.A. No. 17-CI-1147, Order (Franklin, Ky. Circuit Court, July 10, 2018) (filed as Exhibit 2 hereto); *State of Alaska v. Purdue Pharma, L.P., et al*., Case No. 3AN-17-09966CI, Order (Case Motion #8) (3d Jud. Dist. Alaska July 12, 2018) (filed as Exhibit 3 hereto); *In re Opioid Litigation*, No. 400000/2017 (N.Y. Sup. Ct. July 17, 2018) (filed as Exhibit 4 hereto); *State of Ohio ex rel. Mike DeWine, Ohio Attorney General v. Purdue Pharma L.P., et al*., Case No.

1. Plaintiff Sufficiently Pleads Proximate Cause under Montana Law.

a. Under Montana Law, Proximate Causation Is Established if Injury Is the Foreseeable Result of Defendants' Actions.

Under Montana law, proximate cause depends on foreseeability. "A defendant is liable for his wrongful conduct if it is reasonably foreseeable that plaintiff's injury may be the natural and probable consequence of that conduct." *Thayer v. Hicks*, 793 P.2d 784, 795 (Mont. 1990); *see also Oberson v. U.S. Dep't of Agric., Forest Serv.*, 514 F.3d 989, 1000 (9th Cir. 2008) (quoted below) (citing *Busta v. Columbus Hosp. Corp.*, 916 P.2d 122, 135 (Mont. 1996)). "In other words, if one of the reasons that makes a defendant's act negligent is a greater risk of a particular harmful result occurring, and that harmful result does occur, the defendant is generally liable. The test is based on foreseeability." *Cusenbary v. Mortensen*, 987 P.2d 351, 355 (Mont. 1999). It is sufficient that defendants can reasonably foresee *some* injury as a result of their actions, even if not the precise injury a plaintiff suffers. In other words, "the inquiry must be whether the defendant could have reasonably foreseen that his or her conduct could have resulted in an injury to the plaintiff. The particular resulting injury need not have been

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17 CI 261, Decision and Entry (Aug 22, 2018) (filed as Exhibit 5 hereto); *City of Everett v. Purdue Pharma L.P.*, *supra*, 2017 WL 4236062; *accord Travelers Prop. Cas. Co. of Am. v. Actavis, Inc.*, 16 Cal. App. 5th 1026 (Cal. Ct. App. 2017). At least one court has held, in public nuisance cases, that "where the welfare and safety of an entire community is at stake, the cause need not be so proximate as in individual negligence cases." *N.A.A.C.P. v. AcuSport, Inc.*, 271 F. Supp. 2d 435, 497 (E.D.N.Y. 2003); *City of New York v. Beretta U.S.A. Corp.*, 315 F. Supp. 2d 256, 282 (E.D.N.Y. 2004) ("If a defendant's conduct 'remains the dominant and relevant fact without which the public nuisance would not have resulted where and under the circumstances it did,' it may be held liable for setting in motion or being a force in the sequence of events resulting in injury to the public.") (internal citations omitted). Liability turns on whether the harm is a foreseeable result of defendants' action and "[i]ntervening actions, even multiple or criminal actions taken by third parties, do not break the chain of causation if a defendant could reasonably have expected their nature and effect." *City of New York*, 315 F. Supp. 2d at 282 (internal citations omitted).

foreseeable." *Hinkle v. Shepherd Sch. Dist. No. 37*, 93 P.3d 1239, 1245 (Mont. 2004); *Oberson*, 514 F.3d at 1000.

Moreover, under Montana law, the question of proximate cause is a "fact-intensive inquiry" that "must be left to the fact-finder for resolution," except in the rare case where "reasonable minds may reach but one conclusion." *Fisher v. Swift Transp. Co., Inc.*, 181 P.3d 601, 610-11 (Mont. 2008) (citing *Prindel v. Ravalli Cty.*, 133 P.3d 165, 180 (Mont. 2006)); *see also Bassett v. Lamantia*, 417 P.3d 299, 310 (Mont. 2018) (observing that it is the jury's job to "consider[] foreseeability to determine whether the defendant's conduct caused the plaintiff's injury"); *McNair v. Berger*, 15 P.2d 834, 836 (Mont. 1932) ("Whether the injury sustained is the proximate consequence of defendant's wrongful act is ordinarily a question for the jury . . . .").

Thus, the relevant question for proximate cause is not how many sub-steps the Defendants can rhetorically divide the causal chain into; it is whether a reasonable fact-finder could find that the Defendants could foresee that the Tribe's "injury may be the natural and probable consequence of [their] conduct," *Thayer*, 793 P.2d at 795; *see also City of Everett*, 2017 WL 4236062 at *3 ("The Court finds that what Purdue characterizes as nine links of causation could just as easily be characterized as four. . . . Although not as direct as a car accident or slip-and-fall case, this causal chain is still a 'direct sequence,' and it is facially plausible that the involvement of third parties, even criminals, were reasonably foreseeable given the extensive facts of Purdue's knowledge in the pleadings"); *Travelers v. Actavis*, 16 Cal. App. 5th at 1030 ("The California Action and the Chicago Action do not create potential for liability for an accident because they are based, and can only be read as being based, on the deliberate and intentional conduct of

Watson that produced injuries--including a resurgence in heroin use--that were neither unexpected nor unforeseen"). And, as described below, the Tribe alleges facts evidencing just that.

b. The Tribe Alleges in Detail How Its Injuries Were Foreseeable to Defendants.

Here, the Blackfeet Tribe plausibly alleges that but for Defendants' actions in negligently and fraudulently marketing opioids, and failing to report and prevent diversion, the Tribe would not have incurred the costs of widespread addiction and dependence—all of which was foreseeable to Defendants. *See* FAC ¶¶ 434-435, 459-68, 474-76; 478-79; 540-42; 545; 549-63; 586-89; 651, 654-80; 682-90; 694-700; *cf. Summit* Opp. Mem. at § I.C.2.a.

The likelihood of injury to the Blackfeet Tribe was foreseeable to all Defendants. Marketing Defendants misrepresented information they controlled from the time each prescription opioid pill was produced to the present, Distributor Defendants failed to fulfill their duty to prevent diversion by tracking and reporting suspicious orders, and Supply Chain Defendants failed to put proper control systems in place to do so. All Defendants had knowledge about the risks and effects of addiction to the powerful prescription painkillers they manufactured and distributed, respectively. The Complaint details extensive allegations that the Defendants' breaches "foreseeably and substantially caused [their] injur[ies]," and thus the Tribe has properly alleged proximate cause. *Fisher*, 181 P.3d at 609 (internal quotation marks omitted).[16]

[16] Montana law applies to all of the Blackfeet Tribe's state-law claims, while Sixth Circuit law applies to the Tribe's federal RICO claim and its federal nuisance claim. *In re Vertrue Mktg. & Sales Practices Litig.*, 712 F. Supp. 2d 703, 712 n.4 (N.D. Ohio 2010) ("In an MDL proceeding, the transferee court applies the federal law of the circuit in which it is located."), *aff'd*, 719 F.3d 474 (6th Cir. 2013). The Tribe's establishment of proximate cause for its RICO claim is explained in the *Summit* Opposition and addressed below. *See supra* § IV.C. Regardless, similar to Montana law, RICO proximate cause also considers

The Complaint also describes in detail how all Defendants in the supply-chain shared legal responsibility for taking specific steps to prevent diversion, knew of the potential consequences of diversion, and nonetheless intentionally marketed and/or distributed opioids without regard to these known risks because it profited them enormously. *See, e.g.*, FAC ¶¶ 227-47. The Complaint alleges that the Manufacturer and Distributor Defendants knew the information that "would have alerted them to potentially suspicious orders." FAC ¶ 540. This includes the volume (¶ 541) and pattern (¶¶ 543, 561) of opioid orders being placed and filled. Defendants were thus aware of suspicious orders that they were obligated to report and act upon. FAC ¶ 549. The DEA repeatedly warned Defendants of the risk of "enormous harm" caused by diversion, *id.* at ¶¶ 502-03, and yet multiple Defendants have admitted that their monitoring systems were flawed and should have detected certain orders that they shipped as suspicious, *id.* at ¶¶ 565-572, 621. [17]

Plaintiff's allegations are precisely the kind that satisfy Montana's test for proximate causation in a multi-cause case, which hinges entirely on foreseeability. *Oberson*, 514 F.3d at 1000 ("Proximate cause is established when a party could reasonably foresee that its conduct would result in injury.") (citation omitted). In *Oberson*, the Ninth Circuit applied Montana law and found that risks are foreseeable when targeted regulations, established risk-prevention processes, and prior incidents make defendants aware of those risks. *Id.* (finding that the risks of snowmobile accidents

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foreseeability. *See Wallace v. Midwest Fin. & Mortg. Servs., Inc.*, 714 F.3d 414, 419–21 (6th Cir. 2013). None of the Defendants clearly challenge the Tribe's federal nuisance claim on proximate cause grounds. *See* Memorandum in Support of Distributors' Motion to Dismiss First Amended Complaint, ECF No. 23 ("Dist. Mem.") at 18–20; Mfr. Mem. at 34–39; Pharm. Mem. at 4–5. To the extent they do, such arguments fail for the same reasons argued in this section.

[17] Defendants' arguments about intervening causes (Mfr. Mem. at 10–15; Dist. Mem. at 28; Pharm. Mem. at 7–8) are addressed *infra* in §§ II.C.1.c and III.D.

were foreseeable to the U.S. Forest Service because it adopted regulations prohibiting operating a snowmobile under certain circumstances, implemented a trail warranting process, and was aware of a prior incident).

Instead of addressing the Tribe's allegations on foreseeability, the Manufacturing Defendants argue that the Tribe's harms are too remote from their conduct to establish proximate cause. Mfr. Mem. at 6-8. But Montana has no body of law barring claims for remoteness or indirectness alone. *Cf. Busta*, 916 P.2d at 133, 139 (rejecting a freestanding proximate cause requirement related to attenuation, and instead requiring a foreseeability analysis only when the defendant alleges an intervening cause severed the chain of causation). The Manufacturing Defendants' arguments on remoteness and indirectness are based on *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992), and other RICO cases, *see, e.g.*, *Oregon Laborers-Employers Health & Welfare Tr. Fund v. Philip Morris Inc.*, 185 F.3d 957, 963 (9th Cir. 1999), not Montana law, and do not apply to the Tribe's state-law or federal nuisance claims.[18]

c. In this Case, Intervening Acts and Criminal Conduct Are Foreseeable and Do Not Break the Causal Chain.

Defendants attempt to shield themselves from liability by pointing the finger at third-party actors. While Defendants assert that doctors and criminal actors interrupted the casual chain, they ignore a basic principle of Montana tort law: foreseeable intervening causes do not break the causal chain.

In Montana, "if the intervening cause is one that the defendant might reasonably foresee as probable, or one that the defendant might reasonably anticipate under the

[18] *See, e.g., Cleveland Bakers* Opp. Mem. at 5-7 (distinguishing *Perry v. American Tobacco Company*, 324 F.3d 845, 848 (6th Cir. 2003)).

circumstances, then the intervening act does not absolve the defendant of liability." *U.S. Fidelity and Guar. Co. v. Camp*, 831 P.2d 586, 589 (Mont. 1992); *see also Cusenbary v. Mortensen*, 987 P.2d 351, 355-56 (Mont. 1999) (intervening acts by third parties that are foreseeable do not break the chain of causation.). The question a court must consider is "whether the defendant could have reasonably foreseen that his or her conduct could have resulted in an injury to the plaintiff. The specific injury to the plaintiff need not be foreseen." *Fisher*, 181 P.3d at 609-10 (internal citations and quotation marks omitted).

The Montana Supreme Court has provided clear guidance for this analysis:

> We have instructed that if one of the reasons that makes a defendant's act negligent is a greater risk of a particular harmful result occurring, and that harmful result does occur, the defendant is generally liable. Specifically, we consider whether the intervention of the later cause is a significant part of the risk involved in the defendant's conduct, or is so reasonably connected with it that the responsibility should not be terminated.

Fisher, 181 P.3d at 610 (internal citations and quotation marks omitted). Thus, under Montana law, only *unforeseeable* intervening causes break the causal chain.

Defendants argue that the acts of third parties break the causal chain between their misconduct and Plaintiff's injuries. Defendants point both to physicians who wrote prescriptions for opioids and third-parties who engaged in criminal diversion of opioids as purportedly superseding causes that break the causal chain. Yet, both groups' actions were foreseeable, and indeed, their conduct was specifically triggered by the Defendants' malfeasance.

The Tribe alleges that Manufacturer Defendants developed a massive fraudulent scheme to mislead prescribing doctors, patients and the public by misrepresenting the risks and benefits of opioids. *See, e.g.*, FAC ¶¶ 144, 147-317 (describing nine falsehoods directed at doctors and the public); ¶¶ 364-96 (describing the use of KOLs to control

information provided to doctors); ¶¶ 398-409 (describing the use of CMEs to control information provided to doctors). Physicians' decisions to prescribe opioids were not independent of the Marketing Defendants' wrongdoing: those decisions were the intended, actual, and foreseeable result of the defendants' fraudulent conduct.[19] Indeed, the doctors were the intended instruments of the Marketing Defendants' fraud. Sales of opioids could not be increased without the doctors' involvement. Defendants knew they would be involved, and they relied on their involvement.

Similarly, illegal drug activity was an entirely foreseeable consequence of Defendants' failure to control the opioid supply chain as required by law. Indeed, the entire "closed system" for the distribution of opioids exists precisely because misuse, addiction, and an illegal market – along with their concomitant harms to communities – are the entirely foreseeable results of diversion and uncontrolled distribution of these products. *See, e.g.*, FAC ¶¶ 485-489; *see also* H.R. Rep. 91-1444 (1970), *as reprinted in* 1970 U.S.C.C.A.N. 4566, 4575 [at *4575] (need to protect society from scourge of drug addiction); *see also id.* at 4574 (balancing the goals of treating the individual user as "a sick person" and mitigating "the effects of drug abuse on the community"). The

[19] Distributor Defendants' claim that *they* cannot be a proximate cause of Plaintiff's harm for a variety of reasons including because "No injury to any individual opioid user. . . could possibly be incurred unless—sometime after Distributors delivered the medicines to pharmacies—a doctor wrote a prescription that should not have been written, a pharmacist dispensed the drug without presentation of a legitimate prescription, a patient sought to obtain the drug without a legitimate medical need, or a third party improperly obtained the drug from a patient.." Dist. Mem. at 4. This conjecture is both unsupported and therefore inappropriate at the pleading stage, and makes no sense: had Distributor Defendants' fulfilled their duty to put appropriate systems in place to monitor suspicious orders as well as to report and not fill suspicious orders—instead of abandoning this duty on a colossal, nationwide scale—the pharmacies would not have had access to an excessive supply of opioids to continue pumping into the community. Under federal and state law, Distributor Defendants were required to act as gatekeepers specifically in order to guard against the diversion of the highly addictive, dangerous opioid drugs. FAC ¶ 163. Distributor Defendants are a key link in the causal chain, and their actions in continuing to provide pharmaceuticals to fill suspicious orders actually enabled the opioid crisis to exist and expand, proximately causing the harms alleged. Such illogical speculation does not negate the well-pleaded allegations in the Complaint.

Defendants were given privileges and responsibilities with respect to the distribution of controlled substances precisely because the effects of diversion – including the acts of third-parties, criminals, and addicts – were so well known and required vigilance to prevent. *See* FAC ¶¶ 198, 260, 467, 483, 485-93, 498-99, 501, 503, 512.

Defendants' contention that these entirely foreseeable consequences break the causal chain between their failure responsibly to carry out their obligations and the exact consequences that were the reason for these responsibilities in the first place should be rejected.[20]

2. Plaintiff Satisfies the Proximate Cause Standard for Its RICO Claims.

The facts alleged in the Complaint also satisfy the proximate cause standard applicable to RICO claims as set forth in *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992). The Manufacturers argue that Plaintiff cannot satisfy the *Holmes* standard because its injuries are: (1) too remote; (2) too indirect; and (3) too difficult to apportion. Mfr. Mem. at 7-8. This argument should be rejected for the reasons set forth in the *Summit* Opposition at Points I.B.2b and I.C.2.

[20] Contrary to Defendants' argument, the Blackfeet Tribe is not analogous to an insurer who sues the sheriff for negligently letting an inmate escape from work release because the inmate became intoxicated, fell asleep smoking a cigarette, and then the cigarette started a fire in an insured building. *See Kiger v. State*, 802 P.2d 1248, 1251 (Mont. 1990). Here, there is no fortuity, only foreseeability: all of the intervening acts were foreseeable and actually foreseen by policymakers and regulators. It is foreseeable that doctors will write prescriptions for medication that requires a prescription. It is foreseeable that requirements designed to create a "closed system" to prevent the unlawful diversion of opioids, if disregarded and violated, can result in the unlawful diversion of opioids. *See, e.g.*, FAC ¶¶ 485, 498-504, 507. It is foreseeable that someone who becomes addicted to opioids may become addicted to heroin. FAC ¶¶ 6, 17, 103, 134, 667, 670, 939, 1005.

a. Plaintiff's Injuries Are the Direct Consequence of Defendants' Conduct.

In the context of RICO, proximate cause requires that there be "some direct relation between the injury asserted and the injurious conduct alleged." *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 654 (2008). The Sixth Circuit also looks at "whether the plaintiff's injury was a foreseeable consequence of the conduct alleged" and whether "the causal connection between the injury and the conduct is logical and not speculative." *Wallace v. Midwest Fin. & Mortg. Servs., Inc.*, 714 F.3d 414, 419 (6th Cir. 2013). The direct injury requirement ensures that: (1) damages can be properly and efficiently apportioned, (2) no party recovers excessively, and (3) the directly injured are able to vindicate the law by bringing suit to enforce it. *Holmes*, 503 U.S. at 269-70.

As discussed above in connection with Montana law, in this case, there is a direct connection between the conduct alleged and the Tribe's injuries. Those injuries were foreseeable consequences of Defendants' actions, and the causal connection is logical, not speculative. As explained more fully in the *Summit* County briefing, Defendants created two association in fact enterprises, an Opioid Marketing Enterprise and an Opioid Supply Chain Enterprise. Employing certain Front Groups and KOLs, the Manufacturer Defendants concealed the true risks and dangers of opioids from the medical community and the public, including the Plaintiff, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. FAC ¶¶ 320-396. This conduct was intended to, and did, promote the widespread use of dangerous, addictive opioids, causing an epidemic of addiction that injured the Plaintiff "in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction

epidemic." *Id*. at ¶¶ 852-853 (detailing specific costs directly and foreseeably caused by the Manufacturer Defendants' fraudulent activity).

Similarly, the RICO Supply Chain Defendants concealed and suppressed and/or ignored warnings from "third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Defendants were filling on a daily basis—leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market." *Id*. at ¶ 869. This consequence—the creation of a widespread opioid epidemic—was foreseeable, and it in turn directly and foreseeably caused Plaintiff to suffer substantial losses of money and property as a result of the RICO Supply Chain Defendants' fraudulent scheme. *Id.* at ¶¶ 881-86.

The policy considerations set forth in *Holmes* are also satisfied here. Plaintiff's damages may be properly and efficiently apportioned among the Defendants; Plaintiff's RICO damages cannot be sought or recovered by any other party, because they are financial losses suffered directly by the Tribe; and, Plaintiff's recovery is necessary to vindicate the purposes underlying RICO and deter future violations. *See Bank of Am. v. City of Miami*, 137 S. Ct. 1296, 1306 (2017) (relying on *Holmes* to remand a case involving a lengthy causal chain rather than holding that direct causation was absent). Moreover, the existence of victims who both suffer direct injuries (*i.e*. personal injury and economic injury) does not bar Plaintiff's claims because there is a direct causal link between the Defendants' actions and Plaintiff's injury.[21] Additionally, without Plaintiff's

[21] Apportionment and approximation of damages may also be addressed through statistical analysis to establish the necessary causal link to satisfy the question of apportionment. *See Cty. of Cook v. Wells Fargo*, No. 14 C 9548, 2018 WL 1469003, at *8 (N.D. Ill. Mar. 26, 2018) (acknowledging that statistical analysis of aggregative data might establish "the likelihood that a loan modification denied would lead to foreclosure," and sufficiently link Wells Fargo's conduct to at least part of the county's harm); *see also City of Miami*, 137 S. Ct. at 1302 (noting that "[t]he complaint describes statistical analyses that trace the City's financial losses to the Banks' discriminatory practices").

suit, few, if any, victims of the RICO conspiracy will be able to "vindicate the law as private attorneys general." *Holmes*, 503 U.S. at 269-270.

Plaintiff's costs are also directly linked to skyrocketing opioid use and addiction: the express purpose of Defendants' criminal RICO activities. This link distinguishes this case from *City of Cleveland v. Ameriquest Mortgage Securities*, 615 F.3d 496, 504 (6th Cir. 2010) (holding that defendants' legal activities in financing the subprime mortgage market failed to directly cause a panoply of effects, ranging from neglect of property to starting fires, looting, and dealing drugs that were "completely distinct from the asserted misconduct (financing subprime loans)"). The "eyesores, fires, drug deals, and looting" were caused, respectively, by homeowners, negligent or malicious individuals, shoddy construction, independent criminal decisions, and the actions of other companies that financed subprime loans and properties. 615 F.3d at 505. Here, in contrast, the illegal RICO misconduct the Plaintiff has identified matches the harm it suffered: by engaging in a fraudulent scheme to promote the widespread use of addictive opioids, and (as to the RICO Supply Chain Defendants) fostering large-scale diversion, Defendants created the addiction problem that injures Plaintiff's money or property.

Plaintiff's claims are also not derivative of its residents' physical injuries. Instead, Plaintiff suffered direct injury to its revenue generating functions and, in addition, the collective harm imposed on the community. Defendants' conduct was designed to and did create an increased demand for and overabundant supply of their products on a national scale, which generated an opioid crisis in these communities and across the

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Anza v. Ideal Steel Supply Corp., 547 U.S. 451 (2006), and *Canyon County v. Syngenta Seeds, Inc.*, 519 F.3d 969 (9th Cir. 2008), relied on by Defendants, did not address a situation where there is an alleged provable and quantifiable causal link between the defendant's conduct and plaintiff's injury despite multiple links in the causal chain.

country. It is that crisis which has caused the Plaintiff to incur direct costs. Plaintiff seeks to recover its own funds, not "stand in the shoes of nonpurchasing customers" or a business competitor, *see Pik-Coal Co. v. Big Rivers Elec. Corp.*, 200 F.3d 884, 889 (6th Cir. 2000), or recover monies for health insurance plan members required to pay increased health insurance premiums as a result of other smokers, *Perry*, [*supra*,] 324 F.3d at 849. No other, more direct plaintiff will vindicate Plaintiff's important rights.[22]

Although not binding on this Court, it is significant that, in C*ity of Cincinnati v. Beretta U.S.A. Corp*., 768 N.E.2d 1136 (Ohio 2002), the Ohio Supreme Court applied the *Holmes* analysis to assess proximate cause to a city's claims against gun manufacturers. The *Beretta* court found the City's injury flowed sufficiently directly from the actions of the gun manufacturers to satisfy *Holmes.* The claims in *Beretta* were similar to those alleged here. The City of Cincinnati alleged that defendants' negligent marketing and distribution of firearms resulted in creation of an illegal secondary market. The City further alleged that, as a direct result of the defendants' misconduct, plaintiff suffered "actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services." *Beretta*, 768 N.E.2d at 1148. For the same reasons these claims were found sufficient under *Holmes*, the RICO claims at issue should similarly be found sufficiently direct under that same standard.

[22] Manufacturers' reliance on *Sidney Hillman Health Center of Rochester v. Abbott Laboratories*, 873 F.3d 574 (7th Cir. 2017), is inapposite here for two primary reasons. First, unlike *Sidney Hillman*, Plaintiff is not suing the Manufacturers solely for their promotion of opioids for off-label uses. Rather, Plaintiff claims that the Manufacturers utilized unbranded marketing, as part of a larger calculated scheme to increase opioid prescriptions and sales, and directly misrepresented the risks and benefits of opioid use. Second, unlike *Sidney Hillman*, Plaintiff is not an insurance company several steps removed from the causal sequence seeking to recover for derivative injuries that they reimbursed. Rather, as has already been decided in opioid-related litigation, there is a direct causal link between the Manufacturers' intentional marketing and the economic injuries that the Plaintiff received to its commercial and revenue generating functions. *Cf. Travelers*, 16 Cal. App. 5th at 1041 (a nation awash in opioids was neither unexpected nor unforeseen) (quoted above).

The Manufacturers make a new argument not included in the *Summit* briefing. They cite a host of tobacco litigation decisions that dismissed claims at the pleading stage for, among other reasons, lack of causation. However, the Manufacturers' reliance on those cases is misplaced here for two reasons. As the Court is no doubt aware, each of the cases cited by the Manufacturers predates the District of Columbia's 2006 landmark decision in *U.S. v. Philip Morris USA, Inc*., 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in pertinent part, vacated on other grounds in part*, 566 F.3d 1095 (D.C. Cir. 2009), which found various tobacco companies liable for RICO violations premised on strikingly similar allegations, theories, schemes, enterprises and conduct.[23]

Besides predating the District of Columbia decision, none of the cases – with the exception of *Perry* (which as discussed above and at *Cleveland Bakers* Opp. Mem. at 5-7, is distinguishable) is binding authority. Moreover, all of the cases reflect a significantly different causal chain between the injuries at issue and the Tobacco Companies' actions. Specifically, unlike the Tobacco Cases, where there were a host of causes that may have led to an increase in smoking and/or cancer, the increase in opioid prescriptions and addiction is directly traceable to the Manufacturers' unlawful and fraudulent marketing. *See Travelers*, 16 Cal. App. 5th at 1041 ("It is not unexpected or unforeseen that a massive marketing campaign to promote the use of opioids for purposes for which they are not suited would lead to a nation 'awash in opioids.' It is not unexpected or

[23] *Compare U.S. v. Philip Morris*, 449 F. Supp. 2d 1 (D.D.C. 2006) *with Perry v. Am. Tobacco Co*., 324 F.3d 845 (6th Cir. 2003); *Ala. Coushatta Tribe v. Am. Tobacco Co.*, 46 Fed Appx. 225 (5th Cir. 2002); *Serv. Emps. Int'l Union Health & Welfare Fund v. Philip Morris Inc.*, 249 F.3d 1068 (D.C. Cir. 2001); *Association of Washington Public Hosp. Districts v. Philip Morris Inc.*, 241 F.3d 696 (9th Cir. 2001); *Int'l Bhd. of Teamsters, Local 734 Health & Welfare Tr. Fund v. Philip Morris Inc.*, 196 F.3d 818, 825-26 (7th Cir. 1999); *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 239-40 (2d Cir. 1999); *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912 (3d Cir. 1999); *Oregon Laborers-Employers Health & Welfare Tr. Fund v. Philip Morris Inc.*, 185 F.3d 957, 963 (9th Cir. 1999); *State ex rel. Miller v. Philip Morris Inc.*, 577 N.W.2d 401 (Iowa 1998) (collectively, and with the other Tobacco Company cases cited by the Manufacturers, the "Tobacco Cases").

unforeseen that this marketing campaign would lead to increased opioid addiction and overdoses."). Moreover, the Tobacco Cases lack another direct causal link between Plaintiff's injuries and the supply chain claims – *i.e.* the duties that the Manufacturers and Distributors intentionally disregarded which were specifically intended by the drafters of the Controlled Substances Act ("CSA") to prevent the kind of harm alleged – registrants facilitating and/or allowing the widespread diversion of controlled substances out of the legitimate channels into the illicit market. *See* 1970 U.S.C.C.A.N. at 4566 ("[A] closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market."); *U.S. v. Moore*, 423 U.S. 122, 135 (1975) ("Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.") (citations omitted). Third, all of the cases represent attempts to recover a different category of damages than those sought by the Plaintiff. Manufacturers rely particularly on two of the cases, *Oregon Laborers*, and *Ala. Coushatta*, but unlike the plaintiffs in those cases, the Tribe is not seeking to recover merely the "increased costs" of health care (*Oregon Laborers*) or "injuries to the interest in the health and well-being of [their] people" (*Ala. Coushatta*). Rather, as discussed above, Plaintiff seeks to recover for injuries to its commercial and revenue-generating functions.

b. The Actions of Doctors and Criminal Actors Do Not Interrupt the Causal Chain for Plaintiff's RICO Claims.

Just as the actions of third parties does not break the causal chain in this case under Montana law, so, too, under federal RICO standards, neither doctors nor criminal

actors in the illegal drug market render Plaintiff's injuries too remote. *See, e.g., In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 39 (1st Cir. 2013) ("Pfizer now argues that because doctors exercise independent medical judgment in making decisions about prescriptions, the actions of these doctors are independent intervening causes. But Pfizer's scheme relied on the expectation that physicians would base their prescribing decisions in part on Pfizer's fraudulent marketing."); *see also* Restatement (Second) of Torts § 447. The Manufacturers re-argue their *Summit County* position regarding the effect that the presence of doctors and criminal actors have on the causal chain between the Manufacturers' wrongdoing and Plaintiff's injuries. *Compare* Mfr. Mem. at 11-14 *with* Dkt 499-1 at 12-16. Here, Plaintiff's claims are predicated on the same causal chain that exists in *Summit County*, and the Manufacturers' arguments regarding the presence of doctors, or "learned intermediaries," and criminal actors is no more persuasive. Therefore, Plaintiff incorporates prior arguments from *Summit County* regarding the Manufacturers' causation arguments in opposition to the currently raised issues which are substantially identical. *Summit* Opp, Mem. at 38-50, 82-85.

D. Plaintiff Has Sufficiently Pleaded Its Claims under Rules 8 and 9(b).

Federal Rule of Civil Procedure 9(b) requires a plaintiff alleging fraud to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). However, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id.* A complaint "should provide fair notice to Defendants and enable them to prepare an informed pleading responsive to the specific allegations of fraud." *Hale v. Enerco Grp., Inc.*, No. 1:10 CV 00867-DAP, 2011 WL 49545, at *5 (N.D. Ohio Jan. 5, 2011) (Polster, J.) (citation and internal quotation marks omitted).

"Rule 9(b) does not require omniscience; rather the Rule requires that the circumstances of the fraud be pled with enough specificity to put defendants on notice as to the nature of the claim." *Williams v. Duke Energy Int'l, Inc.*, 681 F.3d 788, 803 (6th Cir. 2012) (quoting *Michaels Bldg. Co. v. Ameritrust Co.*, 848 F.2d 674, 680 (6th Cir. 1988)). "Rule 9(b)'s purpose is to ensure fair notice to the defendant, not to test a claim's factual allegations." *Traxler v. PPG Indus., Inc.*, 158 F. Supp. 3d 607, 630 (N.D. Ohio 2016) (Polster, J.) (citation omitted). "So long as a [plaintiff] pleads sufficient detail—in terms of time, place and content, the nature of a defendant's fraudulent scheme, and the injury resulting from the fraud—*to allow the defendant to prepare a responsive pleading*, the requirements of Rule 9(b) will generally be met." *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 504 (6th Cir. 2008) (emphasis added); *see also United States ex rel. Bledsoe v. Community Health Systems, Inc.*, 501 F.3d 493, 509-10 (6th Cir. 2007); *Ferron v. Metareward, Inc.*, 698 F. Supp. 2d 992, 997 (S.D. Ohio 2010). Furthermore, "the Sixth Circuit Court of Appeals has held that Rule 9(b) may be relaxed when there has been a lack of discovery and the information needed for a plaintiff to achieve particularity is held exclusively by the opposing party." *Ferron*, 698 F. Supp. 2d at 997 (citing *Michaels*, 848 F.2d at 680). And, "[i]t is a principle of basic fairness that a plaintiff should have an opportunity to flesh out her claim through evidence unturned in discovery." *Williams*, 681 F.3d at 803 (quoting *Michaels*, 848 F.2d at 680).

1. Rule 9(b) Applies Only to Plaintiff's Montana Common Law Fraud and Statutory Consumer Protection Claims and Its RICO Claims.

Manufacturer Defendants contend that all of Plaintiff's claims should be dismissed for failure to plead with particularity,[24] but the particularity requirement of Rule 9(b) applies only to Plaintiff's fraud-based claims, that is, its Montana common law fraud and Consumer Protection Act claims[25] and its RICO claims. *See* Fed. R. Civ. P. 9(b). For all other claims, the notice-pleading standard under Federal Rule of Civil Procedure 8(a)(2), which requires only "a short and plain statement of the claim showing that the pleader is entitled to relief[,]" governs. *See* Fed. R. Civ. P. 8(a)(2).

The Manufacturers seek to alter this established standard by attempting to recast Plaintiff's nuisance, negligence, unjust enrichment, and civil conspiracy claims into causes of action that "sound in fraud." A claim "sounds in fraud," however, only if the plaintiff "allege[s] a unified course of fraudulent conduct and rel[ies] entirely on that course of conduct as the basis of a claim." *In re Daou Sys., Inc.*, 411 F.3d 1006, 1027 (9th Cir. 2005) (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103 (9th Cir. 2003)). By contrast, "[i]n a case where fraud is not an essential element of a claim, only allegations of fraudulent conduct must satisfy the heightened pleading requirements of

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[24] Manufacturer Defendants cross-reference their Summit briefing; the Tribe cross-references the Summit Opposition accordingly. Further, Manufacturer Defendants advanced similar arguments in the Summit County litigation vis-à-vis mail and wire fraud, and the Tribe incorporates Plaintiffs' response. *Summit* Opp. Mem. at 26-35 [No. 1:18-op-45090-DAP, PageID # 2599-2608]. Manufacturer Defendants' "group pleading" argument (Mfr. Mem. at 54) was rebutted in the Summit Opposition at 34-35 [Page ID # 2607-2608], and at § II.D.2.b *infra*. The *Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538 (E.D. Pa. 2014), *aff'd*, 620 F. App'x (3d Cir. 2015), litigation is distinguished at *Summit* Opp. Mem. at 41, 48 [PageID # 2614, 2621].

[25] The Tribe alleges "deceptive" and "unfair" acts or practices within the meaning of the CPA. *See* FAC ¶¶ 1107-1118. The claim is subject to Rule 9(b) only to the extent it is based on "deceptive" acts or practices. *See Lang v. Ocwen Fin. Servs., Inc.*, No. CV 10-151-BLG-RFC, 2011 WL 1303749, at *6-8 (D. Mont. Mar. 8, 2011), *report and recommendation adopted*, No. CV-1O-151-BLG-RFC, 2011 WL 1258346 (D. Mont. Apr. 1, 2011) (malicious and fraudulent conduct count subject to Rule 9(b); in contrast, court's analysis of the MCPA claim references Rule 8 and omits Rule 9(b)).

Rule 9(b)." *Id*. (*quoting Vess*, 317 F.3d at 1105). "Allegations of non-fraudulent conduct need satisfy only the ordinary notice pleading standards of Rule 8(a)." *Id.; see also Lone Star Ladies Inv. Club v. Schlotzsky's Inc*., 238 F.3d 363, 368 (5th Cir. 2001) ("Where averments of fraud are made in a claim in which fraud is not an element, an inadequate averment of fraud does not mean that no claim has been stated.").

Fraud is an essential element only for the Tribe's Montana common law and statutory consumer fraud claims, and for its RICO claims. Indeed, Rule 9(b) has been found to be inapplicable to nuisance, negligence, negligent misrepresentation, and unjust enrichment claims under Montana law. *See, e.g., Harmon v. Billings Bench Water Users Ass'n*, 765 F.2d 1464, 1467 (9th Cir. 1985) (reversing district court's grant of summary judgment for defendant on attractive nuisance and negligence claim under Montana law and applying notice standard of Rule 8); *Sturgeon v. Carter*, 15 F.R.D. 350, 351 (D. Mont. 1954) ("It is clear under [Rule 8] that to state a cause of action for negligence, detailed pleading is not required."); *Fischer v. Ocwen Loan Servicing, LLC*, No. CV-14-94-BLG-SPW-CSO, 2014 WL 6685987, at *9 (D. Mont. Nov. 25, 2014), *report and recommendation adopted*, No. CV 14-94-BLG-SPW-CSO, 2014 WL 11498231 (D. Mont. Dec. 11, 2014) (applying Rule 8(a)(2)'s requirement of a short and plain statement to Count VIII, negligent misrepresentation and negligence); *Audit Servs., Inc. v. Nelcon, Inc.*, No. CV 13-92-BU-DWM, 2014 WL 12600452, at *3 (D. Mont. Aug. 7, 2014) (unjust enrichment and restitution decided pursuant to "notice pleading standard of Rules 8(a) and 12(b)(6)").

For the remaining claims – fraud, fraudulent acts under the Montana CPA, and RICO – Plaintiff has satisfied the requirements of Rule 9(b).

2. Plaintiff Pleads Its Montana Fraud and RICO Marketing Claims with Sufficient Particularity.

Manufacturer Defendants argue that Plaintiff has not pleaded its Montana fraud and RICO Marketing claims with sufficient particularity. Because the Tribe has identified the fraudulent conduct with sufficient particularity to allow defendants to knowledgeably respond to the pleadings, Manufacturer Defendants' motion should be denied.

The Manufacturers do not seriously contend that they lack sufficient notice of what the Tribe is alleging here. Nor could they. The Complaint, which contains allegations nearly identical to those in the *Summit County* complaint, sets out specific representations made by specific actors at specific times. In addition to twenty-two categories of knowing deceptions and a dozen categories of omitted material facts identified in the Seventh Claim for Relief sounding in Common Law Fraud (FAC ¶¶ 1054-55), the Complaint describes nine categories of falsehoods that the Manufacturer Defendants employed to advance their multi-pronged scheme to change and sustain prescribing habits and public perception, and to increase the demand for opioids (*id.* at ¶¶ 144-317). In addition to specifying the falsehoods, the Complaint explains at length the manner in which the misleading messages were disseminated (*id*. at ¶¶ 318-432). Manufacturers had unique material knowledge and a duty not to deceive the Tribe, which acted in rightful reliance (*id*. at ¶¶ 1057-1060). The Tribe further pleads that the representations and omissions caused it to proceed under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants, which prevented the Tribe from a more timely and effective response (*id*. at ¶ 1062), that the

Tribe's reliance was intended by Defendants (*id*. at ¶¶ 1059-60), and that the Tribe was injured as a result (*id.* at ¶¶ 1062-66).[26]

The Manufacturers argue, however, that Plaintiff is required to identify specific doctors who heard the misrepresentations or issued prescriptions because of the misrepresentations. This contention should be rejected. It is sufficient that Plaintiff has identified the Defendants' fraudulent conduct in detail. *See, e.g., United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc*., 865 F.3d 71, 81 (2d Cir. 2017) (holding that where complaint alleged basis for strong inference that fraud had occurred, it was not necessary for plaintiff to identify specific instances, and noting "emerging consensus" to that effect); *Strom ex rel. United States v. Scios, Inc*., 676 F. Supp. 2d 884 (N.D. Cal. 2009) (where details of fraudulent conduct are provided, plaintiff need not allege specific false claims by specific doctors); *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 49 (D. Mass. 2001) ("[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible."); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp*., 20 F. Supp. 2d 1017, 1049 (S.D. Tex. 1998) (relator satisfied Rule 9(b) by alleging the "basic framework, procedures, the nature of fraudulent scheme, and the financial arrangements and inducements among the parties and physicians that give rise to Relator's belief that fraud has occurred"); *United States ex rel. Pogue v. Am. Healthcorp., Inc*., 977 F. Supp. 1329, 1332-33 (M.D. Tenn. 1997) (permitting relator to omit allegations concerning each instance of fraudulent conduct).[27]

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[26] *See, generally, Paatalo v. First Am. Title Co. of Mont., Inc.*, No. CV-13-128-BLG-SEH-CSO, 2014 WL 2002839, *5-6 (D. Mont. May 14, 2014) (listing elements of fraud).

[27] The cited cases involve the federal False Claims Act and situations that are partially, but not entirely, analogous to the facts of this case. Defendants cite other False Claims Act cases that do require the kind of

Manufacturers suggest that such detail is necessary because, as a matter of "common sense" (based on facts outside the pleading), doctors were unlikely to have been misled. This argument cannot succeed at the pleading stage. Plaintiff has alleged not only that doctors *were* misled, but also a scheme of such depth and penetration that the Court may properly infer that the entire medical community was misled. *See* FAC ¶¶ 318-432. Marketing Defendants misrepresented the most fundamental characteristic of opioids: the degree to which, and the circumstances under which, the drugs are addictive. FAC ¶¶ 43-62. They also misrepresented the extent to which these drugs improve functioning when taken for chronic pain and their relative merits as compared to other treatments for such pain. *See id.* at ¶¶ 237-238. They used Front Groups and KOLs to give their misrepresentations the veneer of scientific objectivity. *Id.* at ¶¶ 319-320. They sponsored Continuing Medical Education programs to present their misstatements as medical "truth." *Id.* at ¶¶ 327-336. They even succeeded in changing the prescribing guidelines for their products to reflect the falsehoods they promulgated. *Id.* at ¶¶ 345-50.

In this context, it makes no sense to say that Plaintiff must identify specific doctors to whom misrepresentations were made and specific prescriptions affected by those misrepresentations. In the climate the Marketing Defendants created, no doctors

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claim-by-claim specific detail held to be unnecessary in the authorities cited above. For the reasons described in the text, however, in the extraordinary factual context of this case as compared to cases arising under the False Claims Act, the authorities that have found such detail unnecessary are more properly applicable. Two of the defendants' False Claims Act cases, *Yuhaz v. Brush Wellman, Inc.*, 341 F.3d 559, 564 (6th Cir. 2003) ("*Yuhaz*") and *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 830 (6th Cir. 2018) ("*Prather*") are especially inapplicable here. *Yuhaz* is inapposite because here Plaintiff did not create the complexity that obviates the need to plead the details the Manufacturers demand; the complexity of the schemes at issue arise from the Marketing Defendants' multi-pronged marketing scheme using sales detailers, publications, websites, Front Groups, and KOLs. *Prather* does not support dismissal in this case because it recognizes the applicable pleading standard here, related to "complex and far-reaching fraudulent scheme[s]." *Prather*, 892 F.3d at 830.

had access to the true facts about opioids and no prescription was unaffected by the Marketing Defendants' falsehoods.[28] The Marketing Defendants' false and fraudulent marketing prevented *all* doctors from engaging in proper risk/benefit analyses when prescribing opioids. Their misrepresentations affected not only how many opioid prescriptions were written, but the periods of time for which they were written; the extent of cautions passed along to the patient; the degree of monitoring for signs of tolerance, dependence, and/or addiction; and (e) the early identification of patients showing troubling symptoms of tolerance, dependence, and/or addiction. In light of the extensive detail the Complaint provides about each of the Marketing Defendants' falsehoods and the pervasive means by which they were disseminated to the entire medical community, Plaintiff need not identify particular doctors who heard, and were affected by, those messages.

Moreover, Plaintiff should not be required to allege at the pleading stage facts that it may not be required to prove at trial. In *In re Neurontin Mktg. & Sales Practices Litig. v. Pfizer, Inc*., 712 F.3d 21 (1st Cir. 2013), the First Circuit affirmed a jury verdict in favor of a third-party payor against a pharmaceutical company for fraudulent off-label marketing. Even though not a single physician in the entire multidistrict litigation had testified that he or she prescribed Neurontin because of defendants' marketing, the First Circuit upheld the jury's finding of proximate cause, because expert testimony at trial

[28] Manufacturers attempt to draw a distinction between physician reliance on misrepresentations and physician reliance on true statements, contending that Plaintiff must identify specific instances of the former. *See* Mfg. Mem. at 54, *citing United States v. Caronia*, 703 F.3d 149, 164-65 (2d Cir. 2012). But this distinction is meaningless in the context of this case, because the Marketing Defendants' false statements were intertwined with any true statements they may also have made. In *Caronia*, by contrast, the defendant was criminally prosecuted for off-label marketing; the issue was whether true statements about off-label uses may give rise to such prosecution. The case in no way suggests that a plaintiff must parse out, at the pleading stage, the extent to which outright and pervasive falsehoods about the most fundamental characteristics of a dangerous drug affected any particular doctor's conduct.

established that pharmaceutical marketing does, in fact, have an impact on physicians. Indeed, the expert proof at trial established that doctor-by-doctor proof of causation was unnecessary in light of "the well-recognized unreliability in the field of healthcare economics of asking doctors individually whether they were influenced by the many methods of off-label marketing." 712 F.3d at 30.

To the extent that the Manufacturers rely on *City of Chicago v. Purdue Pharma L.P.*, 2015 WL 2208423 (N.D. Ill. May 8, 2015) ("*City of Chicago*") and *Travelers Indemnity Co. v. Cephalon, Inc.*, 620 F. App'x 82 (3d Cir. 2015) ("*Travelers*"), both of those cases were previously addressed in the *Summit* MTD briefing and have no relevance to the allegations at issue in this case.[29]

Nor are the cases involving the standard of causation cited by the Manufacturers applicable to the level of detail that must be provided under Rule 9(b).[30] For the reasons discussed above, Plaintiff adequately alleges that the Manufacturers' conduct caused the Tribe's injury. The adequacy of these allegations to satisfy the requirements of

[29] *City of Chicago* is notably an early decision in those proceedings that involved a complaint that was later superseded by more detailed allegations. The allegations in *City of Chicago* have also been similarly superseded by additional factual detail in the Plaintiff's current FAC. Likewise, *Travelers*, is inapplicable because there, "the Amended Complaint itself refers to very few specific communications by the defendants regarding off-label use of Actiq and Fentora." *Travelers*, 32 F. Supp. 3d at 552-53. The stark contrast between Travelers' failure to specifically identify a very few specific communications regarding off-label use (whether analyzed by the Eastern District of Pennsylvania or the Third Circuit), and Plaintiff's detailed allegation of a complex fraudulent marketing scheme that began in 1996 prevent any comparison between *Travelers* and Plaintiff's claims.

[30] *In re Bextra & Celebrex Mktg. Sales Practice and Prod. Liability Litig.*, MDL No. 1699, 11-CV-00310, 2012 WL 3154957, at *6 (N.D. Cal. Aug. 2, 2012) ("the mere fact that prescriptions were written does not prove causation") (emphasis added); *Cent. Reg'l Emps. Ben. Fund v. Cephalon*, No. Civ.A.09-3418 (MLC), 2010 WL 1257790, at *4 (D.N.J. Mar. 29, 2010) (plaintiffs had not alleged any material misrepresentations or omissions by Cephalon – only that Cephalon had engaged in off-label marketing); *In re Actimmune Mktg. Litig.*, No. C 08-02376 MHP, 2009 WL 3740648, at *11 (N.D. Cal. Nov. 6, 2009) (plaintiffs had "not sufficiently amended their complaint to cure the causation and reliance deficiencies in their UCL fraudulent prong claim."); *Sidney Hillman, supra*, 873 F.3d at 577 (discussing issues that compound the problem of indirect causation, or indirect injuries).

proximate cause, however, is an inquiry entirely distinct from the requirements of Rule 9(b), which apply only to allegations of fraud.

For the reasons set forth in the *Summit* Opposition and above, Plaintiff pleads its fraud and RICO Marketing Claims with sufficient particularity to satisfy Rule 9(b).

3. Plaintiff's RICO Supply Chain Claim is Pleaded with Sufficient Particularity

Manufacturer and Distributor Defendants argue that Plaintiff fails to plead with particularity the mail and wire fraud allegations that support the RICO Supply Chain claim. This argument turns on Defendants' attempt to cast the RICO Supply Chain mail and wire fraud claims as claims of affirmative misrepresentation. But, as explained in the *Summit* Opposition, Plaintiff alleges a fundamentally omission-based claim that also included misrepresentations made in furtherance of the overall omissions. Specifically, Defendants had a duty, under the CSA and its implementing regulations, to identify and report suspicious orders of prescription opioids, yet failed to do so in order to increase and maintain high quotas for the manufacture and distribution of their drugs, thereby unlawfully expanding the market. FAC ¶¶ 799-809. The mail and wire fraud statutes, moreover, do not require a misrepresentation or omission; a scheme or artifice to defraud will suffice.[31] Even so, Plaintiff pleaded misrepresentations and omissions with sufficient particularity to notify Defendants of the claims against them.

[31] Misrepresentation is merely one means by which either crime may be committed. Section 1341 refers to "any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretense, representations or promises. 18 U.S.C. § 1341; 18 U.S.C. § 1343. The essence of mail and wire fraud is taking money or property belonging to another and using those instrumentalities in furtherance of the scheme. A misrepresentation is not required. *Carpenter v. United States*, 484 U.S. 19, 26-28 (1987); *McNally v. Gray*, 483 U.S. 350, 359 (1987) (mail fraud reaches "false promises and misrepresentations as to the future as well as other frauds involving money or property") (emphasis added); *Bridge*, *supra*, (describing a classic fraud-by-concealment scheme, with no communications to the victims).

Plaintiff details the specific circumstances constituting the overall fraudulent scheme, including instances where the Defendants omitted material information, the overall methods they used, and instances in which some Manufacturers and all of the Distributors made misrepresentations.[32] In addition to the list of false and misleading statements (FAC ¶¶ 150-317, 575-578, 580-583, 703, 711-712, 732, 766, 772-776, 779, 806, 809, 831-832), Plaintiff alleges specific examples of the Defendants' material omissions, including their awareness of specific orders, awareness of competing Manufacturer and Distributor Defendants' orders, and their failure to report them, including that the Defendants had a duty to make a full and complete disclosure regarding their compliance with the CSA, and failed to do so while allowing hundreds of millions of pills to be diverted. FAC ¶¶ 258, 296, 474-476, 485, 497-505, 507-509, 511-516, 528-529, 531-572, 586-592, 596-606, 608-619, 621-635, 648, 714-720, 733, 750-763, 801-806, 808-810, 817, 825. For example, Mallinckrodt was prosecuted for failing to report suspicious orders, including the orders through which "Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics." FAC ¶¶ 499-500, 569. The Complaint details similar enforcement actions against each of the Distributor Defendants, all of which confirm that the Distributor Defendants were aware of and refused to report suspicious orders. FAC ¶¶ 564-572. Plaintiff also alleges that all of the Distributor Defendants, and some of the Manufacturer Defendants, made additional affirmative misrepresentations that furthered the common purpose of the

[32] A "RICO claim does not require any proof of affirmative misrepresentations because the omission of material facts suffice to prove the predicate acts of mail or wire fraud." *In re Duramax Diesel Litig.*, 298 F. Supp. 3d 1037, 1083 (E.D. Mich. 2018) (citation omitted); *see also In re Whirlpool Corp.*, 684 F. Supp. 2d 942, 961 (N.D. Ohio 2009). Plaintiff must only allege their "theory of fraudulent omissions with enough specificity to provide Defendants with fair notice of the claims." *Duramax*, at 1056 (citing *United States v. Walgreen Co.*, 846 F.3d 879, 880-81 (6th Cir. 2017)).

Opioid Supply Chain Enterprise. FAC ¶¶ 564-72, 573-85, 652-700, 726, 729, 806, 808-09.

These allegations are sufficient to satisfy Rule 9(b) as to a scheme to defraud by omission. "Rule 9(b) does not require fraud-by-omission claims to specify the time, place, and specific content of an omission as precisely as would a . . . false representation claim." *Whirlpool*, *supra*, 684 F. Supp. 2d at 961. The allegations described above provide the Distributor Defendants with sufficient "who, what, when, and how" to distinguish the cases cited in footnote six of Defendants' brief.[33]

The Manufacturers' argument that Plaintiff must, but has failed to, identify specific pharmacies is incorrect and irrelevant to Plaintiff's mail and wire fraud claims. As a preliminary matter, Plaintiff's Complaint identifies numerous enforcement actions taken against the majority of the Manufacturers involving their failure to report suspicious orders. FAC ¶¶ 458, 500, 565, 569, 758-762. The Manufacturer and Distributor Defendants well know which pharmacies were at issues in the enforcement actions against them and which pharmacies that they should have identified to the DEA as suspicious. The Complaint alleges that the Manufacturer and Distributor Defendants

[33] *Paatalo v. J.P. Morgan Chase Bank, N.A.*, No. CV-10-119-BLG-CSO, 2011 WL 13130862, at *10 (D. Mont. May 18, 2011) (plaintiff's complaint "simply echoe[d] the language of the RICO statute," "provide[d] few details as to specific times, places, or roles played by individual defendants in the alleged scheme," and "the list of predicate acts is conclusory and without concrete factual allegations against the specific defendants"); *Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 405 (6th Cir. 2012) (failure to allege the dates of emails that were sent between 2005 and 2006, specifically addressed to the plaintiffs by a single defendant, did not provide sufficient particularity); *Prater v. Livingston Ave. Child Care, LLC*, No. 2:14-CV-490, 2015 WL 1439322, at *5 (S.D. Ohio Mar. 27, 2015) (wire fraud allegations based solely on misrepresentation in relation to one agreement were dismissed because the plaintiff could not provide any facts to support the claim, failed to identify any fraudulent statements used to induce reliance, failed to explain why such statements were fraudulent and failed to provide where and when the fraudulent statements were made); *Arnold v. Alphatec Spine, Inc.*, No. 1:13–cv–714, 2014 WL 2896838, at *12 (S.D. Ohio June 26, 2014) (dismissal for plaintiffs' failure to identify which patients had undergone medically unnecessary surgery as a result of alleged misrepresentation); *Hot-Shot Motorworks v. Falicon Crankshaft Components*, No. 3:13 CV 1322, 2014 WL 346435, at *5 (N.D. Ohio Jan. 30, 2014) (dismissal because "[p]laintiffs fail[ed] to include *any* required detail in their Amended Complaint with respect to the alleged fraud" other than two bare bones allegations). *Accord* Dist. Mem. 9 n.6 (citing cases).

were in possession of sophisticated prescriber and patient-level data which alerted them to prescribing and usage trends and, furthermore, that the Manufacturer and Distributor Defendants were actually aware of pill mills and that diverted drugs were traveling along drug corridors like the "oxy express" and the "blue highway", and did nothing to stop it. FAC ¶¶ 543-48, 551-53, 556-59, 561-63, 571, 589, 601, 611, 614-618, 621-625, 632, 636-50, 747-63, 801, 809. Furthermore, the Distributors have put forward no authority for their hoped-for requirement that Plaintiff identify pharmacies as part of their Rule 9(b) obligations. This argument is therefore, meritless.

Finally, the Distributors cannot plausibly argue that Plaintiff fails to allege a mail and wire fraud scheme that was used to deprive someone of money or property. This argument is a complete adoption of an identical argument asserted by the Distributors in *Summit County*. Plaintiff therefore incorporates its argument from the *Summit* Opposition at 33-34. The entire purpose of the Opioid Supply Chain Enterprise was to deprive people of money or property by refusing to identify, report and reject suspicious orders. FAC ¶¶ 476, 498-499, 513-16, 564-85, 799-804, 809-10, 816-17, 820. This scheme evidences fundamental dishonesty, unfairness, improper dealings, and an absence of moral uprightness, as well as fraudulent misrepresentations and omissions. *United States v. Van Dyke*, 605 F.2d 220, 225 (6th Cir. 1979); *United States v. Jamieson*, 427 F.3d 394, 402 (6th Cir. 2005).

a. Plaintiff Does Not Improperly "Group Plead."

The Manufacturer and Distributor Defendants both argue that Plaintiff failed to satisfy Rule 9(b) because Plaintiff improperly "group plead" the allegations against Defendants. This argument is adopted wholesale from the Manufacturer and Distributor Defendants' briefs in *Summit County* and Plaintiff incorporates the arguments from the

Summit Opposition at 34-35. The cases cited by the Manufacturers[34] and Distributors[35] involve relatively small numbers of defendants who were charged with making a relatively small number of misrepresentations, and situations in which the allegations do not support the inference of responsibility for the representations of another. Therefore, those cases are distinguishable from the complex far-reaching fraud allegations in this case, where Plaintiff also alleged the misrepresentations made by each of the RICO Manufacturer and Distributor defendants regarding their respective marketing and supply chain activities.

4. Plaintiff Pleads Its Claims against the Generic Manufacturers with Sufficient Particularity.

The Generic Manufacturers argue that the marketing claims against them should be dismissed because their business model does not involve promotion of their products, in effect denying that the allegations of the Complaint are true as to them. Such a contention is clearly outside the scope of a motion to dismiss, as it relies on facts outside the pleading, assumes the falsity of the allegations in the Complaint, and calls upon the Court to draw inferences in favor of the movant, rather than the pleader. *See Doe v. Miami Univ.*, 882 F.3d 579, 588 (6th Cir. 2018) (on a motion to dismiss, a court "must construe the complaint in the light most favorable to the plaintiff and accept all allegations as true"); *In re Fair Fin. Co.*, 834 F.3d 651, 656 n.1 (6th Cir. 2016), *reh'g denied* (Sept. 23, 2016) ("As a general rule, matters outside the pleadings may not be considered in ruling on a 12(b)(6) motion. . . ."). Nor is it obviously the case that generic

[34] *Hoover v. Langston Equip Assocs., Inc.*, 958 F.2d 742, 745 (6th Cir. 1992) (dismissing fraud claims because, unlike Plaintiff's allegations, the plaintiffs had articulated general averments of fraud attributed to "the defendants" and "the complaint [did] not enable a particular defendant to determine with what it is charged"); *Cataldo v. U.S. Steel Corp.*, 676 F.3d 542, 551 (6th Cir. 2012).

[35] *See* Dist. Mem. 9 n.7 and 10 (citing cases).

manufacturers lack economic incentives to engage in unbranded promotion, nor that their business models necessarily exclude such promotion.

In order to give their argument the veneer of legal authority, the Generic Manufacturers (and, indeed, the Manufacturers as well) cite *New York v. Actavis, PLC*, No. 14 CIV. 7473, 2014 WL 7015198, at *26 (S.D.N.Y. Dec. 11, 2014), *aff'd sub nom. New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015), but the *Actavis* case provides no basis for this Court to disregard the allegations of the Complaint. In *Actavis*, the court held an evidentiary hearing on a motion by the State of New York for a preliminary injunction. Following the hearing, based on the evidence presented, the court made certain findings of fact on the specific record applicable to the specific drug in the case (Namenda IR, used in the treatment of Alzheimer's disease). The Generic Manufacturers may not substitute the findings of fact of a different court, in a different case to which the Tribe was not a party, involving a different drug, for proof at any stage in this case, but even less may it credit such findings in contradiction to the allegations of the Tribe's Complaint. The Generic Manufacturers will have the opportunity to deny, and to attempt to disprove, the allegations of the Complaint with respect to their participation in the fraudulent marketing of opioids, but their contention that the allegations of the Complaint are untrue cannot be adjudicated on this motion.

The remainder of the Generic Manufacturers' argument that the Tribe has not pleaded its marketing claims against them with sufficient particularity is a variant of the "group pleading" argument raised by other defendants, and is equally without merit. *See Summit* Opp. Mem. at 34-35. In particular, in this instance, the Generic Manufacturers are subsidiaries and sibling companies to name-brand manufacturers. *See* FAC ¶¶ 45, 47,

64, 74. Plaintiff alleges that the various corporate entities within the corporate family work together and promote opioids. With respect to the Actavis entities, for example, Plaintiff alleges that "*Each of these defendants and entities* is owned by Defendant Allergan PLC, which uses them to *market* and sell its drugs in the United States." *Id.* at ¶ 45 (emphasis added). Similarly, Plaintiff alleges that "Teva USA and Cephalon, Inc. *and their DEA registrant subsidiaries and affiliates* (collectively, "Cephalon") work together to manufacture, *promote*, distribute and sell *both brand name and generic versions* of . . . opioids in the United States, the State, and Plaintiff's Community." *Id.* at ¶ 49 (emphasis added). And, with respect to Mallinckrodt, Plaintiff alleges "Mallinckrodt plc, Mallinckrodt LLC, *and SpecGX LLC* and their DEA registrant subsidiaries and affiliates (together "Mallinckrodt") manufacture, *market*, sell and distribute pharmaceutical drugs throughout the United States, and in the State, and Plaintiff's Community." *Id.* at ¶ 74 (emphasis added). Plaintiff further alleges that "Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, *and opioids generally*, in a campaign that consistently mischaracterized the risk of addiction." *Id.* at ¶ 197 (emphasis added).

Plaintiff also alleges that the Marketing Defendants engaged in unbranded advertising and promotion. *See* FAC ¶¶ 197, 198, 319, 412-413, 701-713. Such advertising benefited not only branded opioids, but generic opioids as well, as it increased the market for all opioid medications through false and fraudulent misrepresentations. *See, e.g., id.* at ¶ 412 ("Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising."), *id.* at ¶ 701

(marketing defendants engaged in unbranded advertising "to increase sales, revenue, and profit from their opioid products."). Moreover, because each of the Generic Manufacturers is affiliated with a branded manufacturer, the Court may infer that unbranded advertising and promotion was carried out by the corporate family on behalf of the company's branded *and* generic products.

The Generic Manufacturers also argue that the Tribe's supply-chain and diversion claims fail uniquely as to them because, they argue, the Complaint fails to allege specific facts about them. This argument, too, should be rejected.

Plaintiff's claims concerning the failure to control the supply chain and prevent diversion do not sound in fraud and are not subject to the heightened pleading requirements of Rule 9(b). Instead, these claims need only comply with the notice-pleading standard under Federal Rule of Civil Procedure 8(a)(2), which requires only "a short and plain statement of the claim showing that the pleader is entitled to relief[,]" governs. *See* Fed. R. Civ. P. 8(a)(2). To the extent that the Generic Manufacturers seek to impose a higher pleading standard with respect to these claims, the Tribe respectfully incorporates the argument with respect to pleading standards made by Summit County in its omnibus opposition to all defendants' motions to dismiss.

In any event, the Tribe adequately alleges its supply-chain claims against these defendants. The Tribe alleges that "under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances." FAC ¶ 481. It further alleges that "*each of the Defendants* was required to register with the DEA to manufacture and/or distribute Schedule II controlled substances." *Id.* at ¶¶ 483 (emphasis added). Plaintiff alleges that "Defendants failed to report suspicious orders, prevent

diversion, or otherwise control the supply of opioids following into communities across America" and that "[d]espite the notice described above, and in disregard of their duties, Defendants continued to pump massive quantities of opioids despite their obligations to control the supply, prevent diversion, report and take steps to halt suspicious orders." *Id.* at ¶ 564; *see also* ¶¶ 513-516, 539-550. Plaintiff is not required to plead specific evidence to support its claims, nor to provide specific examples of enforcement actions against each defendant, even where such examples are provided with respect to some. This is especially true because the Tribe's claims are not created by the Defendants' statutory and regulatory duties, but rather arise from their parallel state duties to exercise reasonable care in delivering their dangerous products. Thus, Plaintiff need not prove, much less allege, that a defendant was the subject of any enforcement action in order to establish a defendant's liability.

5. Plaintiff Adequately Pleads Claims Against the Pharmacy Defendants.

The Pharmacy Defendants argue that Plaintiff has not adequately pleaded claims against them as pharmacies. Pharm. Mem. at 3-4. Plaintiff does not allege violations of statutes or regulations applicable specifically to retailers who sell opioids. To the extent that Pharmacy Defendants also act as distributors, however, they may be subject to the same duties as other distributors (including where applicable to set the standard of care, the requirements under the CSA). Plaintiff's allegations against the Pharmacy Defendants are based, in part, on the duties of these defendants as distributors, to control the supply chain for the dangerous drugs they distributed and to implement effective procedures to guard against diversion.

In addition, the Pharmacy Defendants are liable for their role in the supply chain as *retailers* under the same theories as apply to their role as distributors. In both roles, the Pharmacy Defendants participate in the supply chain for dangerous opioid medications and in both roles, they have duties to act with due care in supplying these drugs. Plaintiff clearly alleges that these defendants, like their co-defendants who operate only at the wholesale level of the supply-chain, failed to implement a system to detect and prevent diversion. That the appropriate systems may have been different for their wholesale distribution than for their retail operations does not change the fact that the Pharmacy Defendants failed to control the supply chain at either point at which they operate. Plaintiff sufficiently alleges these failures. *See* FAC ¶¶ 494, 541, 591.

III. PLAINTIFF HAS PROPERLY PLEADED ITS STATE LAW AND FEDERAL COMMON LAW CLAIMS

A. Plaintiff Has Adequately Pleaded Its Federal Common-Law Nuisance Claim.

1. Plaintiff Has Pleaded All the Required Elements of Federal Nuisance.

The Supreme Court has observed that federal nuisance common law "adapts to changing scientific and factual circumstances." *Am. Elec. Power Co. v. Connecticut*, 564 U.S. 410, 423 (2011). Federal common law of nuisance reshapes "the old law of public nuisance . . . to fit the 'realities of modern technology.'" *United States v. Ira S. Bushey & Sons, Inc.*, 363 F. Supp. 110, 120 (D. Vt.), *aff'd*, 487 F.2d 1393 (2d Cir. 1973). Other Circuit courts have observed that the Supreme Court's jurisprudence "reflects [a] broad understanding" of the public nuisance doctrine and that "[p]ublic nuisance traditionally has been understood to cover a tremendous range of subjects." *Michigan v. U.S. Army Corps of Engineers*, 667 F.3d 765, 771-772 (7th Cir. 2011). Finally, tribes, political

subdivisions and private parties have been held to be appropriate plaintiffs under the cause of action. *See id.* (tribe in federal nuisance suit).

The elements of a federal common law nuisance claim are "simply that the defendant is carrying on an activity that is causing an injury or significant threat of injury to some cognizable interest of the complainant." *Illinois v. City of Milwaukee*, 599 F.2d 151, 165 (7th Cir. 1979), *rev'd on other grounds, City of Milwaukee v. Illinois and Michigan*, ("*Milwaukee II*"), 451 U.S. 304 (1981). The Second Restatement, which "has been a common reference point for courts considering cases arising under federal common law" *Michigan v. U.S. Army Corps of Engineers*, 758 F.3d 892, 900 (7th Cir. 2014), defines a public nuisance as "an unreasonable interference with a right common to the general public." Restatement (Second) of Torts § 821B (1) (1979) (explaining that common rights include "public health, the public safety, the public peace, the public comfort or the public convenience"). Under any kind of public nuisance law – state or federal – "unreasonable" refers primarily to the interference, not the defendant's conduct. William L. Prosser and W. Page Keeton, The Law of Torts § 52 (5th ed. 1984). Intent is not a required element under federal nuisance law. *Bushey*, 363 F. Supp. at 120.

The Tribe has fulsomely described an unreasonable interference to its public rights in its FAC, describing in over 180 pages, Defendants' reckless and unreasonable practices. FAC ¶¶ 144-635. These practices have not only led to increased crime, addiction, deaths, destruction of public spaces, property crime, and increased tribe expenditures, but has also created a public health/safety emergency as well as a palpable climate of fear, distress, dysfunction and chaos in the community. FAC ¶¶ 898, 890.

Defendants' actions and the resulting harms are the quintessential embodiment of a Second Restatement and/or federal public nuisance.

2. Application of Federal Common Law is Appropriate Here.

Defendants' conduct as alleged in the FAC is interstate in nature and creates the types of nuisances which require "the need for a uniform rule of decision." *Illinois v. City of Milwaukee*, 406 U.S. 91, 105 n.6 (1972) ("*Milwaukee I*"). In these cases, it is appropriate to fashion a single federal standard, rather than rely on a patchwork of separate state nuisance standards. Additionally, federal nuisance is especially appropriate here because Plaintiff's status as a federally-recognized tribe – a sovereign – implicates "uniquely federal interests." *Tex. Industries, Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 640 (1981). Indeed, "Indian tribes are domestic dependent nations that exercise inherent sovereign authority over their members and territories." *Oklahoma Tax Commission v. Citizen Band Potawatomi Indian Tribe of Oklahoma*, 498 U.S. 505, 509 (1991). That status significantly heightens the federal nature of this controversy.

Defendants' actions and their resulting impacts were, and continue to be, inherently transboundary in nature. FAC ¶¶ 636-650, 896-897. Defendants engaged in a nation-wide, fraudulent marketing and distribution scheme. FAC ¶¶ 475, 543. Defendants' marketing and distribution of opioids were driven by national policies, coordination, plans, and procedures that were carefully crafted and implemented using national, regional, state, and local prescriber- and patient-level data. FAC ¶ 475. When individual states, counties, cities, or tribal communities implemented stricter measures to curb the infiltration of opioids, out-of-state suppliers filled the gaps. FAC ¶¶ 636-650. Prescriptions for opioids manufactured and distributed in one jurisdiction were regularly transported for sale in another. FAC ¶ 639 (detailing the investigation and arrest of a

group transporting over 800-1,200 30 mg oxycodone pills every two weeks from California for distribution in Billings, Montana). Prescriptions written in one jurisdiction would often be filled in another. FAC ¶¶ 636-650. Defendants were fully aware of the transboundary effect of their manufacturing and distribution scheme and profited from it. These practices, as well as the unique federalism concerns presented by tribal grievances generally, justifies a need for the application of federal common law.

3. Federal Common Law is Not Displaced by the CSA or DEA Regulations.

Defendants claim that federal common law claims of public nuisance claims are displaced by the Controlled Substances Act ("CSA") and various Drug Enforcement Administration ("DEA") regulations because the statute and regulations purportedly "speak[] directly to the question at issue." Dist. Mem. at 18; Pharm. Mem. at 4. As an initial matter, DEA regulations are irrelevant to the inquiry because, as the Ninth Circuit in *Native Village of Kivalina v. ExxonMobil Corp.* has observed, "*Congressional* action, not executive action, is the touchstone of displacement analysis." 696 F.3d 849, 858 (9th Cir. 2012) (emphasis added); *see also Shell Offshore, Inc. v. Greenpeace, Inc.*, 2015 U.S. Dist. LEXIS 76306, at *19 (D. Alaska June 12, 2015) ("it is the relevant statutes, and not the Coast Guard's subsequent safety and security zone regulations, that are the focus of the displacement analysis").

Defendants misrepresent the proper application of the displacement test. Courts are clear that while the test for displacement is plainly stated, the "existence of laws *generally applicable* to the question is not sufficient; the applicability of displacement is an issue-specific inquiry." *Native Village of Kivalina*, 696 F.3d at 856 (emphasis added). The salient question then, is "whether Congress has provided a sufficient legislative

solution to the particular [issue] to warrant a conclusion that [the] legislation has occupied the field to the exclusion of federal common law." *Michigan*, 667 F.3d at 777.

Congress provided no such legislative solution in the CSA. While Defendants are correct that the CSA itself "sets forth criteria they must meet to achieve and maintain registration," as well as "packaging and labeling," "forms" and "records" requirements [Dist. Mem. at 18-20] (which Defendants did in fact violate), such criteria hardly amount to a complete occupation to the exclusion of a national standard of liability. If it were, we would probably not find ourselves where we are now – wrestling with the worst man-made public health epidemic in modern medical history. Moreover, the CSA does not at all speak to the reckless and national marketing scheme of the type Defendants engaged in here, which is one basis for the Tribe's nuisance claims.

Also important is that Congress explicitly intended that the CSA would not be the end-all for the oversight of illicit drug enterprises. The CSA is clear that it does not "occupy the field [of controlled substances] . . . to the exclusion of any State law on the same subject matter." 21 U.S.C. § 903. In finding that the Federal Water Pollution Control Act did not displace the state of Illinois' right to claims federal common-law nuisance, the court in *People of State of Ill. ex rel. Scott v. City of Milwaukee, Wisc.* found as persuasive "the express intention of Congress to allow the states to establish tougher standards of performance." 366 F. Supp. 298, 301 (N.D. Ill. 1973).

The Supreme Court itself has determined that certain federal statutory schemes do not displace federal common law public nuisance. For example, in *Milwaukee I*, Illinois sued Milwaukee and other cities to prevent them from dumping sewage into Lake Michigan. *See* 406 U.S. at 93. Writing for a unanimous Court, Justice Douglas ruled that

the federal common law of public nuisance had not been displaced, despite the fact that Congress had by that time "enacted numerous laws touching interstate waters." *Id.* at 101. Laws that touched on the issue at hand were not enough, and thus the common law action could move forward. *Id.* at 108.[36]

Many lower courts have adopted the reasoning in *Milwaukee I*, demonstrating that the decision still remains vital. For example, In *Michigan v. U.S. Army Corps of Engineers*, the Seventh Circuit denied defendants' motion to dismiss the federal nuisance claims of a Native American tribe and five states. 667 F.3d at 771 (2011). There, the plaintiffs claimed that an invasive carp species, if unabated, would pose irreversible damage to the Great Lakes. *Id.* at 768. Citing *Milwaukee I*, the court addressed multiple federal statutes potentially affecting displacement. *Id.* at 778-780. The court determined that while Congress was well aware of the problems posed by invasive carp species and had authorized federal agencies to take certain actions, it fell "far short of the mark." *Id.* at 780. The statutes that defendants claimed were displacing federal common law were found to be less comprehensive than Congress's air or water pollution schemes and also did not provide "for any enforcement mechanism or recourse." *Id.* at 779-780. Emphasizing that federal nuisance "exists to provide a uniform rule for interstate disputes that will serve the national interest," the court rejected defendants' arguments that the claim was displaced. *Id.* at 773, 800. Like the statutes discussed in *Michigan*, the CSA is

[36] To be clear, six months after *Milwaukee I*, Congress passed sweeping amendments to the Federal Water Pollution Control Act. Nine years after that, the Court decided in *Milwaukee II* that those amendments displaced federal common law in the area. 451 U.S. 304 (1981). Critical to *Milwaukee II*'s analysis, however, was that under the new regime "every point source discharge is prohibited unless covered by a permit," and that "there is no room for courts to attempt to improve on that program." *Id.* at 318. In contrast, the CSA does not govern *every* distributor or manufacturer transaction or statement and, for reasons articulated in this response, there is certainly room for federal common law to improve on controlled substances oversight. Even under *Milwaukee II* Plaintiff's federal nuisance claim is not displaced.

not as robust as the air or water pollution schemes, and also does not provide an adequate enforcement mechanism or adequate recourse for the entities effected by the scourge of opioids.

And, most recently, in *In re Ingram Barge Co.*, a federal district court denied summary judgment on plaintiff's federal nuisance claims which were based on the destruction of federal property. No. CV 13 C 3453, 2016 WL 1450027, at *17, 2016 U.S. Dist. LEXIS 49319, at *141 (N.D. Ill. Apr. 13, 2016). Addressing displacement, the court distinguished the federal regulatory regime involved in the Supreme Court case of *Am. Elec. Power Co.*, noting, "[Defendant] fails . . . to establish the RHA's likeness to the Clean Air Act or the Clean Water Act as an 'all-encompassing regulatory program' supervised by one expert agency. . . . Although the RHA touches on the issue at hand . . . . laws that 'touch[] on the issue at hand [are] not enough . . .'" 2016 WL 1450027, at *17-18, 2016 U.S. Dist. LEXIS 49319, at *142.

Here, the CSA does not touch at all on many of the FAC's allegations. *See, e.g.*, FAC ¶¶ 147-317 (detailing Defendants' multiple falsehoods); FAC ¶¶ 317-436 (detailing sophisticated campaign to convince the medical community of falsehoods, including payments to key opinion leaders); FAC ¶ 585 (Defendants' misleading public statements of efforts to work with law enforcement to curb infiltration of opioids). Moreover, as *In re Ingram* explains, the Clean Air Act ("CAA"), which was the statutory regime at issue in Defendants' cited case of *American Electric Power Co.*, is a markedly robust and complete one with its own private enforcement mechanism. 564 U.S. 410, 423-25 (2011). Because the private enforcement mechanisms of the CAA provide "the same relief the plaintiffs seek by invoking federal common law," the *American Electric* decision saw "no

room for a parallel track." *Id.* The CSA, however, lacks this feature. It "does not specify a *private* remedy for those aggrieved by violations of the CSA." *Ringo v. Lombardi*, No. 09-4095-CV-C-NKL, 2010 WL 3310240, at *2 (W.D. Mo. Aug. 19, 2010). And, federal oversight of opioid diversion is largely dependent on DEA regulations, which (as explained above) are irrelevant to the displacement analysis.

The Supreme Court in *Georgia v. Tenn. Copper Co.*, explains that when the states joined the union, and in so doing, abandoned their right to abate foreign nuisances by force, "they did not thereby agree to submit to whatever might be done . . ." 206 U.S. 230, 237 (1907). Therefore, *a fortiori*, the nation's Indian tribes, who *involuntarily* gave up such rights and received the federal government's protection in exchange, must be entitled to the same right of action. Defendants' arguments would essentially consign sovereign tribes to dependency upon the whims of federal agents to protect them from incursions by reckless manufacturers, promotors and distributors of lethal painkillers.[37] There is no evidence that Congress had that intention through their promulgation of the CSA. Defendants' motion to dismiss the Blackfeet Tribe's federal nuisance cause of action should be rejected.

B. Plaintiff Has Adequately Pleaded Its State Law Statutory Public Nuisance Claims.

Montana statutory law defines a nuisance as "[a]nything that is injurious to health . . . . so as to interfere with the comfortable enjoyment of life or property. . . ." MONT. CODE ANN. § 27-30-101(1). In turn, "comfortable enjoyment of life" includes the safety, health or morals of the public. Restatement (Second) of Torts § 821B (2)(a). The

[37] Indeed, Defendants themselves argue that tribes are not subject to the protections of state drug laws. [Dist. Mem. at 18-20] (citing Montana state drug laws, and stating "Indian tribes have no role in this comprehensive scheme . . .").

Montana Code further explains that public nuisance, as opposed to private nuisance, is "one which affects, at the same time, an entire community or neighborhood or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal." MONT. CODE ANN. § 27-30-102(1). Finally, "'public nuisance,' as defined and construed, requires little if any . . . intent, being virtually a crime of absolute liability." MONT. CODE ANN. § 45-8-111, Editors' Notes, Criminal Law Commission Comments.

The FAC sets forth in detail Defendants' actions which led to the public nuisance. Specifically, Defendants employed a sophisticated campaign to convince the medical community and the public that opioids were safe, when they were not. FAC ¶¶ 917, 924, 929, 932, 933, 935. Defendants failed to prevent diversion of their opioids to illicit channels. FAC ¶¶ 15, 37, 932. Defendants' misconduct fostered black markets for diverted prescription opioids and a concomitant rise in heroin and fentanyl abuse. FAC ¶¶ 9, 934. By flooding Montana and the Blackfeet Reservation with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that Defendants knew or should have realized were being diverted for illicit purposes, Defendants caused this opioid crisis. FAC ¶¶ 481, 542.

The FAC describes the consequences of this conduct to the Blackfeet Tribe, consequences that the Centers for Disease Control has called a "public health epidemic," what the U.S. Surgeon General has deemed an "urgent health crisis," and what one Blackfeet Tribe senior tribal member has described as the Tribe's "modern-day small pox." FAC ¶¶ 17, 688. Specifically, the First Amended Complaint details severe and far-reaching public health, social services, and criminal justice consequences, including the

fueling of addiction and overdose from illicit drugs such as heroin. FAC ¶¶ 19, 928. The costs are borne by the Tribe and other similarly situated tribes. FAC ¶ 20. These necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placements, among others. FAC ¶¶ 19, 928 674, 945, 1027.

In short, Defendants have created and maintained a public nuisance, prohibited by MONT. CODE ANN. § 27-30-101(1), through their ongoing conduct of marketing, promoting, distributing, and selling opioids, which are dangerously addictive drugs, in a manner which caused prescriptions and sales of opioids to skyrocket on the Blackfeet Reservation, flooded the Blackfeet Reservation with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Blackfeet Nation and its residents.

1. Plaintiff Has Alleged an Interference with a Public Right.

Defendants first attempt to characterize the Blackfeet Tribe's allegations as simply an amalgamation of private, personal injury claims suffered by Plaintiff's residents rather than rights of the public and community of the Blackfeet Tribe. Dist. Mem. at 16; Pharm. Mem. at 6. Defendants' argument fails on two fronts. First, this case is not about whether individual residents of the Tribe have a right to be personally and individually safe from defective products. Nor is it about whether particular individuals in particular circumstances with particular medical conditions abused or misused or were improperly prescribed opioids. While it is true that thousands of the Plaintiff's residents have been personally touched by the opioid crisis, the Tribe's public nuisance claim does

not seek recovery based on, or for, the personal injuries of any individual resident. Instead, the Tribe alleges that the Defendants engaged in conduct that creates widespread harm and widespread costs that are "borne by Plaintiff" itself. FAC ¶ 19.

Second, Defendants ignore clear statutory language and generally accepted principles of law when they claim that the opioid epidemic cannot constitute a public nuisance because it does not interfere with a public right. A public right may be – and here has been – infringed by conduct that also creates a multitude of private harms and tragedies. Public rights and private ones are distinct, but they are not mutually exclusive or contradictory. Montana's public nuisance statute specifically contemplates that "[a]nything that is injurious to health" is a public nuisance. MONT. CODE ANN. § 27-30-101(1). The Second Restatement provides an even more expansive definition, directing the court to consider whether the activity interferes with the **"**public health, the public safety, the public peace, the public comfort or the public convenience." Restatement (Second) of Torts § 821B (2)(a); *see also id.* at comment b ("public nuisances include[s] interference with the public health . . .").

The DEA also considers the opioid epidemic to be a public health crisis. In 2006, the DEA stated that, "the illegal distribution of controlled substances has a substantial and detrimental effect on *the health and general welfare of the American people*" and that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm." FAC ¶ 503 (emphasis added).

Recently, the New York Supreme Court expressly rejected, on two separate occasions, the exact argument put forth by both Distributor and Manufacturer Defendants here:

> [I]t suffices to note the defendants' failure to establish why public health is not a right common to the general public, nor why such continuing, deceptive conduct as alleged would not amount to interference; it can scarcely be disputed, moreover, that the conduct at the heart of this litigation, alleged to have created or contributed to a crisis of epidemic proportions, has affected a considerable number of persons.

In re Opioid Litigation, No. 400000/2017, 2018 WL 3115102, at *22 (N.Y. Sup. Ct. June 18, 2018); *see also In re Opioid Litigation*, 400000/2017, at 13 (N.Y. Sup. Ct. July 17, 2018) (same) (filed as Exhibit 4 hereto).

Similarly, in *State of West Virginia, ex rel. Morrisey v. AmerisourceBergen Drug Corp.*, the court found that plaintiffs sufficiently pleaded their public nuisance claims, because defendants infringed on plaintiffs' rights:

> . . . to be free from unwarranted injuries, addictions, diseases and sicknesses and have caused ongoing damage, hurt or inconvenience to WV residents exposed to the risk of addiction to prescription drugs, who have become addicted, and/or have suffered other adverse consequences from the use of the addictive prescription drugs distributed by Defendants . . .

C.A. No. 12-C-141, 2014 WL 12814021, at *10 (Boone Cty. Cir. Ct., W. Va. Dec. 12, 2014).

Defendants argue that the Tribe engages in "cursory allegations" and "never identifies any specific act by any of the Moving Defendants that violated any law or interfered with any public right." This argument would require the Court to ignore all the factual allegations in Plaintiff's three hundred page First Amended Complaint detailing each Defendant's violations of a myriad of state and federal laws and regulations. *See, e.g.*, FAC ¶¶ 745 (civil and criminal penalties related to Purdue's OxyContin); FAC ¶ 753 (record $150 million fines for McKesson distribution practices); FAC ¶ 750 (Cardinal Health $44 Million fine for CSA violations); *see also* FAC ¶¶ 44, 84, 453-54, 456-58, 500, 565-572, 606, 608-619, 621-29, 737-46, 757, 762.

Defendants also claim that the Tribe does not sufficiently allege that Defendants exercise control over the prescribing practices of doctors, or detail how patients use the drugs they are prescribed. This argument, however, misconstrues the public nuisance instrumentality alleged in the FAC. Plaintiff's public nuisance claim is not about a defective product. Rather, the Tribe seeks redress and abatement of Defendants' unlawful marketing and distribution activities which foreseeably and continually fuel illegal secondary markets for opioids on the Blackfeet Reservation. Courts have rejected Defendants' "lack of control" argument in similar circumstances. *See James v. Arms Tech., Inc.*, 820 A.2d 27, 52-53 (N.J. 2003); *Cincinnati v. Beretta U.S.A. Corp.*, 768 N.D.2d 1136, 1142 (2002); *see also Monroe* Response to Motion to Dismiss § III.E.3 (rebutting similar argument and citing cases.).

Plaintiff has adequately alleged an interference with a public right. Defendants worked together to create one of the greatest interferences to a public right –"the worst man-made epidemic in modern medical history – the misuse, abuse, and over-prescription of opioids." FAC ¶ 2. Such allegations meet the definition of "public right" set forth under Montana law. Defendants' claims to the contrary are disingenuous and should be rejected.

2. Plaintiff's Public Nuisance Claim is Not a Disguised Product-Liability Claim.

Defendants argue that Plaintiff's public nuisance claims are "essentially products liability claims for economic damages masquerading under the guise of nuisance law." Mfr. Mem. at 34. Defendants fail to cite any Montana authority rejecting a public nuisance claim because the claim involved a product. A number of jurisdictions, however, have examined Defendants' argument and rejected it. *See, e.g., People v.*

Conagra Grocery Prods. Co., 17 Cal. App. 5th 51 (2017) (upholding public nuisance verdict against lead paint companies based on marketing for residential use more than fifty years earlier); *Gov't of the United States V.I. v. Takata Corp*., 67 V.I. 316, 410 (Super. Ct. 2017) (rejecting defendants' claim that the claim was a "product liability claim under the guise of public nuisance" because the "argument ignores the crux of Plaintiff's allegations, which largely pertain to [defendants'] conduct in affirmatively misrepresenting and concealing information regarding a known hazardous defect, rather than [defendants'] initial manufacture and placement of the defective product in the stream of commerce."); *Cty. of Santa Clara v. Atl. Richfield Co*., 137 Cal. App. 4th 292, 309-10 (2006) (holding "[a] public nuisance cause of action is not premised on a defect in a product or a failure to warn but on affirmative conduct that assisted in the creation of a hazardous condition"); *City of Cincinnati v. Beretta U.S.A. Corp*., 768 N.E.2d 1136, 1142 (Ohio 2002) (finding "that under the Restatement's broad definition, a public-nuisance action can be maintained for injuries caused by a product if the facts establish that the design, manufacturing, marketing, or sale of the product unreasonably interferes with a right common to the general public").

In *Beretta*, the court rejected the gun industry's arguments that their conduct, which the city alleged "ensure[d] the widespread accessibility of the firearms to prohibited users . . . [and thereby] fostered the criminal misuse of firearms," could not form the basis of an actionable public nuisance claim, ruling that "the city should be permitted to bring suit against the manufacturer of a product under a public nuisance theory, when, as here, the product has allegedly resulted in widespread harm and

widespread costs to the city as a whole and to its citizens individually." 768 N.E.2d at 1140-1143.

Defendants ignore these cases, and rely instead on distinguishable ones. *See, e.g.*, *State v. Lead Indus. Ass'n. Inc*., 951 A.2d 428 (R.I. 2008) (overruling trial court's refusal to dismiss the public nuisance count not because the claims sounded in product-liability, but because the complaint did not allege all of the elements of public nuisance); *Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp*., 273 F.3d 536, 540 (3d Cir. 2001) (rejecting the public nuisance claim because the allegations were that a *lawful* product was being *lawfully* placed in the stream of commerce); *Ashley Cty. v. Pfizer*, 552 F.3d 659 (8th Cir. 2009) (affirming the lower court's dismissal not because public nuisance involved a product, but because the pleadings didn't sufficiently allege proximate cause, and noting that the defendants' manufacture, sale and distribution complied with the law and the intervening criminal acts broke the causal chain); *City of Perry v. Procter & Gamble Co.*, 188 F. Supp. 3d 276, 291 (S.D.N.Y. 2016) (declining to conclude that a nuisance claim can arise out of the legal sale or use of a product because the court had not considered such a claim before); *Detroit Bd. Of Educ. v. Celotex Corp*., 493 N.W.2d 513, 520 (Mich. Ct. App. 1992) (deciding in a *private nuisance* claim not to hold asbestos manufacturers liable under a nuisance theory because they no longer had control over the nuisance and thus could not abate it).[38] Unlike Defendants' cases, Blackfeet Tribe's First Amended Complaint alleges all of the necessary elements of

[38] Defendants also cite to what appears to be a draft version of the *Restatement (Third) of Torts* for the contention that "the common law of public nuisance is an inapt vehicle for addressing the conduct at issue" in cases of dangerous products. No Montana case adopts the public nuisance section of the *Restatement (Third) of Torts*, nor of any other section of the *Restatement (Third) of Torts*.

public nuisance, that the opioid epidemic was caused by Defendants' *unlawful* conduct, and that the nuisance can be abated by Defendants.

Plaintiff's claim is straightforward public nuisance: Defendants' conduct in creating the opioid epidemic has resulted in a public nuisance which the Tribe must now pay to abate. Plaintiff's focus on Defendants' conduct, rather than the product, falls squarely within the line of cases cited above, in which courts have allowed public nuisance cases relating to products to go forward. As Defendants say in their brief, "[p]ublic nuisance is about the abatement of annoying or bothersome activities." Mfr. Mem. at 36. Plaintiff's public nuisance claims seek to abate Defendants' annoying or bothersome activities which caused the opioid epidemic.

3. An Interference to Property Rights is Not Required.

Defendants argue that the Tribe's public nuisance claim fails because Montana law of nuisance is "concerned with the misuse of, or interference with, land or real property." Mfr. Mem. at 35. In Montana, there is no requirement that public nuisance must involve an interference with land or property. In Montana, "*[a]nything* that is injurious to health, indecent or offensive to the senses . . . so as to interfere with the comfortable enjoyment of life *or* property" can be a sufficient injury to establish a nuisance. MONT. CODE ANN. § 27-30-101 (emphasis added). To suggest that a public nuisance must include an interference with property ignores the rest of the statute, which specifically states that a public nuisance can be something that interferes with the "comfortable enjoyment of life." In a throwaway footnote, Defendants say that the "tribe is not a living being and so cannot claim damages for interference with its 'life' or 'personal enjoyment.'" Dist. Mem. at 16, n. 15. No authority is cited for this contention. Contrary to Defendants' suggestion, a public entity can suffer a loss of "personal

enjoyment" and interference with "life." In fact, in tobacco litigation in the 1990s, a Montana District Court found just that, when it refused to dismiss the State's public nuisance claim because "methods utilized by the Defendants in marketing those products or suppressing information" resulted in an injury "to health . . . so as to interfere with the comfortable enjoyment of life . . . ." *State v. Philip Morris*, 1998 Mont. Dist. LEXIS 732, at *30-31 (1st Jud. Dist. Mont., Lewis and Clark Cty. 1998).

There is simply no Montana precedent holding otherwise and Defendants' cases are highly distinguishable. For example, *Graveley Ranch v. Scherping*, 782 P.2d 371 (Mont. 1989) was cited by Defendants as holding that "the presence of exposed lead batteries on defendants' property . . . sufficiently interfered with plaintiff's use of property for grazing so as to constitute a nuisance." Mfr. Mem. at 35. Defendants conveniently omitted key language from the court's holding, that the lead batteries were "injurious to health." *Graveley Ranch*, 782 P.2d at 373. The court did not examine whether damage to real property was required to establish a nuisance cause and provides no support for Defendants' argument that a public nuisance must involve interference with real property.

Defendants next cite *State ex rel. Dept. of Environmental Quality v. BNSF Ry. Co.*, 246 P.3d 1037 (Mont. 2010) in support of their argument that public nuisance requires interference with land or real property. However, nowhere in *Environmental Quality* is the question of interference with real property ever raised, rather the sole issue was whether the contaminated groundwater and soil pollution "affect[ed], at the same time, an entire community or neighborhood or any considerable number of persons." *Id.* at 1043.

Defendants similarly come up short when they argue that *State ex rel. Fields v. Dist. Ct. of First Judicial Dist*., 541 P.2d 66 (Mont. 1975) supports the proposition that "Montana public nuisance cases . . . focus on the use of real property." Mfr. Mem. at 35-36. In *Fields*, the court overruled the lower court's determination that keeping a dangerous dog on property was a public nuisance. The dog was the point. *Id.* at 68. The Court in *Kasala v. Kalispell Pee Wee Baseball League*, 439 P.2d 65, 66-69 (Mont. 1968) likewise overruled the lower court's determination that a Pee Wee baseball league's use of a playground constituted a public nuisance. Because there is no Montana precedent requiring an allegation of damage to real property in order for a claim for public nuisance to proceed, Defendants' arguments should be rejected.

In addition, the "property" argument made by Defendants was argued and rejected in another case, *State of New Hampshire v. Purdue Pharma*. There, the court expressly rejected the Defendants' argument:

> Indeed, numerous other jurisdictions that, like the New Hampshire Supreme Court, look to the Restatement (Second) of Torts to guide their analysis of public nuisance claims have expressly concluded that "[a]n action for public nuisance may lie even though neither the plaintiff nor the defendant acts in the exercise of private property rights."

State of New Hampshire v. Purdue Pharma, at *27-28 (N.H. Sup. Ct. Sept, 18, 2018) (filed as Exhibit 1 hereto).

C. Plaintiff Pleads a Montana Common-Law Public Nuisance Claim.

The Tribe's second claim for relief under Montana state public nuisance law includes absolute public nuisance at common law, and in the alternative, qualified public nuisance at common law. An absolute nuisance is a nuisance, "the substance . . . of which is not negligence, which obviously exposes another to probable injury." *Barnes v. City of Thompson Falls*, 979 P.2d 1275, 1278 (Mont. 1999) (internal citation omitted). On the

other hand, qualified nuisance is a "nuisance dependent on negligence [that] consists of anything lawfully but so negligently or carelessly done or permitted as to create a potential and unreasonable risk of harm, which, in due course, results in injury to another." *Id.* Both have been validly pled.

As articulated in detail within its FAC and throughout this response, Defendants engaged in a nationwide, fraudulent, and reckless manufacturing and distribution scheme. FAC ¶¶ 144-635. Specifically, Manufacturer Defendants poured millions of dollars into carefully calculated marketing scheme intended to push the use of opioids, when they knew for a fact that they were not safe. FAC ¶¶ 144-468. Distributor Defendants intentionally and unreasonably distributed and sold opioids that Defendants knew would be diverted into the illegal, secondary market and would be obtained by persons with criminal purposes. FAC ¶¶ 469-635.

Defendants assert that they did not engage in negligent conduct, and therefore they cannot be liable under the qualified nuisance theory. To be clear – Defendants' conduct was *beyond* negligent – it is best characterized as a reckless disregard for human life to achieve maximum profit. But it is sufficient, in this context, that the Tribe alleges throughout its Complaint, and particularly with respect to its negligence cause of action, that Defendants *did* engage in negligent conduct, allegations that must be accepted as true at this stage. *See, e.g.*, FAC ¶ 982 (Defendants were required to exercise a high degree of care and their conduct violated their duties to Plaintiff); FAC ¶ 983 (reasonably prudent distributors would have prevented diversion); FAC ¶ 983 (reasonably prudent manufacturers would have abstained from reckless marketing activities); FAC ¶ 1022 (detailing how Distributor Defendants violated federal and state law.).

Defendants erroneously argue that they are immune from absolute public nuisance because they engage in activities "subject to express statutory authorization." Dist. Mem. at 14. But Defendants' own cited case explains that this type of immunity only lies where it "can be fairly stated that the legislature contemplated the doing of *the very act* which occasions the injury." *Barnes v. City of Thompson Falls*, 979 P.2d 1275, 1279 (Mont. 1999) (emphasis added) (internal citation and quotation omitted). For example, in *Tally Bissell Neighbors, Inc. v. Eyrie Shotgun Ranch, LLC*, 228 P.3d 1134, 1140 (Mont. 2010), the Montana Supreme Court cited *Barnes* in finding that although a statutory scheme provided for the existence of gun ranges, and "protected shooting ranges explicitly from planning, zoning, community decay, litter, disorderly conduct, and criminal nuisance . . . . [it made] no mention of civil nuisance liability." The court therefore allowed the nuisance claims to proceed. *Id.* Here, the law does not even come close to authorizing Defendants to engage in the alleged conduct, much less authorizing the "very act" that is alleged to have created the nuisance.

Most importantly, a Montana court has previously rejected this *exact* argument, put forth in the analogous tobacco litigation:

> Defendants contend that because Montana law authorizes the sale of cigarettes, the State's nuisance claim must fail. The State's nuisance claim, however, is not based on the sale of tobacco products. Rather, it is based on Defendants' alleged deceitful and misleading conduct in promoting tobacco products; the alleged deceptive manipulation of nicotine in tobacco products; the alleged targeting of minors; and alleged misrepresentation to the public regarding the safety of tobacco products. Since the State's claim is not based on the sale of tobacco products but on the methods utilized by the Defendants in marketing those products or suppressing information, the Court concludes that the State has adequately pled a cause of action for public nuisance and that it should not be dismissed.

State v. Philip Morris, 1998 Mont. Dist. LEXIS 732, at *30. Therefore, Defendants' arguments relating to absolute nuisance are meritless and should be rejected.

Defendants argue that "Montana does not recognize a cause of action for 'common law public nuisance.' Rather, Montana has long defined the law of nuisance by statute . . ." Mfr. Mem. at 39. However, the Montana Supreme Court has stated that "[f]or the written law to effect a repeal of (the common law), the intent of the legislature to bring about the change must be clear . . ." *Haker v. Sw. Ry. Co.*, 578 P.2d 724, 727 (Mont. 1978). There is no such clear intent in Montana's public nuisance statute to dispense of the common law cause of action of public nuisance.

Defendants support their contention with an isolated quotation from a case from 1982 which states that the public and private nuisance statutes "are but crystallizations of the common law." Mfr. Mem. at 39. They do not explain why this sentence would serve to abrogate over a century's worth of common law nuisance principles. Nor could they – the case itself details the robust history of the common law cause of action within Montana. *Belue v. State*, 649 P.2d 752, 754-55 (Mont. 1982) (reviewing common law public nuisance and citing a cases from 1928 and 1957); *see also Mugler v. Kansas*, 123 U.S. 623, 672-673 (1887) (for more than a century, courts have recognized the applicability of public nuisance claims when the conduct of a defendant interferes with the public health and safety of the community). The better explanation is that in Montana, statutory and common law public nuisance causes of action both exist and that Plaintiff has adequately pleaded both.[39]

[39] To the extent they are applicable, the Tribe incorporates all arguments made in its "statutory nuisance" section herein.

In that Plaintiff has adequately pled all of its state and federal nuisance claims, all of Defendants' arguments are meritless and should be rejected.

D. Plaintiff Has Properly Pleaded Negligence Claims Against All Defendants.

"A negligence claim requires the plaintiff to establish that the defendant owed a legal duty, and there existed a breach of that duty, causation, and damages." *Newman v. Lichfield*, 272 P.3d 625, 631 (Mont. 2012) (citation omitted). These elements are outlined in detail in the FAC. *E.g.*, FAC ¶¶ 975-1050 (Sixth Claim for Relief). Defendants deny the existence of any legal duty, complain that statutes and regulations do not create a private right of action, infirmly demand Rule 12(b)(6) dismissal based on their version of facts, and cross-reference prior briefing.[40]

Defendants are wrong at every turn. They misconstrue the facts pled in an attempt to apply their legal citations, but even then mischaracterize Montana law. Duty is a legal issue, but negligence generally, and foreseeability specifically, are not. Defendants misstate Montana law by arguing that they win, at the pleadings stage, merely by claiming that an intervening superseding cause overrides their own culpable conduct. Defendants also misstate Montana law by suggesting that a specific "relationship" is a prerequisite to a legal duty. And, all of these arguments miscast the Tribe's pleadings. The Tribe is not trying to hold Defendants liable for the unforeseeable crimes of rogue third parties; rather, the Tribe is pleading Defendants' liability for Defendants' conduct. Defendants' private-right-of-action arguments also are straw-men because the Tribe has

[40] *See* Pharm. Mem. at 9-10 (heavily relying on prior briefing); Dist. Mem. at 20 (citing prior briefing). In response, the Tribe cross-references the plaintiffs' prior responses. *See* Summit Opp. Mem., at 69-85 [No. 1:18-op-45090-DAP, Doc. #59, PageID # 2642-58].

Defendants also incorporate their proximate causation arguments, to which the Tribe has responded here at §II.C.

not pleaded that federal or state laws or regulations create a private right of action. The Tribe does contend that these authorities prove the standard of care breached by Defendants. There is no authority for dismissing a complaint under Rule 12(b)(6) merely because it points to operative standards of care.

1. Plaintiff Has Properly Pleaded the Existence of a Duty.

Under Montana common law, Defendants owe a duty of care not to deceitfully market dangerously addictive drugs nor to deliver them into illicit channels. Plaintiff is not seeking to enforce the statutes or regulations breached by Defendants through a private cause of action, but rather these authorities are cited by the Tribe to define the standard of care applicable under common law negligence.

a. Defendants Owe a Common Law Duty of Reasonable Care.

The FAC alleges that the devastation of crippling drug addiction and its injury to the Tribe was foreseeable to Defendants. FAC ¶¶ 981, 984, 992, 994, 997, 1020. "[U]nder the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances." *Id*. at ¶ 481. "By flooding Montana and Plaintiff's Community with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm." *Id*. The FAC further explains that Defendants should have known, and indeed acknowledged, their obligations and the serious consequences resulting from the abdication of those obligations. *Id*. at ¶¶ 498-512, 586-635. Marketing Defendants designed and implemented a marketing strategy built on deception to cover-up the drugs' dangers. *Id*. at ¶ 144. Defendants knew how

dangerous these pills were, which is why they had to join together in deceptive schemes to artificially inflate the drug quotas. *See id*. at ¶¶ 764-827 (describing deliberate enterprises).

The FAC thus alleges Defendants' knowledge at great length, including 32 pages describing the Distributor Defendants' knowledge of the obligations they were breaching, their orchestrated inflation of drug quotas, and their pretense of working with law enforcement. FAC ¶¶ 498-572. Distributor Defendants nonetheless claim that the harm to the Tribe allegedly was not foreseeable. Dist. Mem. at 23. As a matter of Montana law and federal procedure, Defendants' protestations denying foreseeability are an insufficient basis for dismissing the Tribe's complaint.

Montana follows Justice Cardozo's frequently quoted statement in *Palsgraf v. Long Island Rd. Co.*,[41] that, "[t]he risk reasonably to be perceived defines the duty to be obeyed." *Fisher v. Swift Transp. Co.*, 181 P.3d 601, 607 (Mont. 2008) (cit. & quot. mark om.). "Whether a party owes a legal duty depends largely on whether the allegedly negligent act was foreseeable." *Gourneau ex rel. Gourneau v. Hamill*, 311 P.3d 760, 762 (Mont. 2013) (citation omitted). "Foreseeability as it relates to the duty element of negligence is measured on a scale of reasonableness dependent upon the foreseeability of the risk involved with the conduct alleged to be negligent." *Lopez v. Great Falls Pre-Release Services, Inc.*, 986 P.2d 1081, 1086-87 (Mont. 1999).[42] "[T]he focus is on what the defendant could or could not foresee," and "[t]he jury in a negligence action is tasked

[41] 162 N.E. 99 (N.Y. 1928).

[42] *Overruled, in part, Samson v. State*, 69 P.3d 1154, 1159 (Mont. 2003) (repudiating language in *Lopez* "which would require a jury to determine the foreseeability of a plaintiff's 'specific injury'" and reaffirming a prior decision that "juries must be instructed that the specific injury to the plaintiff need not have been foreseen") (*Lopez* is cited in Mfr. Mem. at 17-18, omitting disclosure to the Court that the case was overruled in part).

with deciding whether the risk in question . . . was foreseeable to the defendants." *Newman*, 272 P.3d at 631.[43]

Defendants relatedly argue that as a matter of law they have no duty to protect against the conduct of others. Mfr. Mem. at 17-18; Dist. Mem. at 24; *cf.* Pharm. Mem. at 9. As an initial matter, Defendants misstate the issue; here liability is based on *their own conduct* in *inter alia* misrepresenting dangerously addictive drugs as not being dangerously addictive and placing the drugs into illicit distribution channels notwithstanding non-delegable duties to guard against diversion. Because the Tribe seeks to hold each Defendant liable, in negligence, for Defendants' own conduct, Defendants' protracted discussion of whether the Tribe can hold each Defendant liable for the criminal conduct of a third party is inapposite.[44]

Independently, Defendants rely on an erroneous version of Montana law. The Tribe's negligence claim cannot be dismissed merely because Defendants contend that their conduct is overshadowed by the intervening acts of others. This is because the Montana Supreme Court expressly has rejected the argument that the wrongful acts of third parties can never form the basis for liability as a matter of law. *See Starkenburg v.*

[43] As these cases make clear, under Montana law, foreseeability is implicated in both duty and proximate cause in cases like this. *See Thayer v. Hicks*, 793 P.2d 784, 795-96 (Mont. 1990); *see also Fisher*, 181 P.3d at 609; *Busta v. Columbus Hospital Corp.*, 916 P.2d 122, 133-34 (Mont. 1996).

[44] Manufacturer Defendants invite this Court to apply plaintiffs' losses in gun cases here. Mfr. Mem. at 19. Plaintiffs' successes in litigation against gun manufacturers has been previously briefed and the gravamen of persuasive jurisprudence addressing Defendants' arguments has rejected them in well-reasoned opinions. *See* Summit Opp. Mem., 9, 12-14, 71-72, 80-81 [No. 1:18-op-45090-DAP, Doc. # 59, PageID # 2582, 2585-87, 2644-45, 2653-54]. Manufacturer Defendants misplace reliance on decisions that seek to impose liability based on criminal assaults perpetrated by third parties rather than the actions of the defendants themselves. *See Shadday v. Omni Hotels Mgmt. Corp.*, 477 F.3d 511, 513 (7th Cir. 2007) (disagreeing with *District of Columbia v. Beretta, U.S.A., Corp.*, 872 A.2d 633, 641-42 (D.C. 2005) (cited in Mfr. Mem. at 19), and characterizing the decision as an example of "plaintiffs who seek to impose liability on a third party who failed to prevent a criminal's attack"). *Contrast also McCarthy v. Olin Corp.*, 119 F.3d 148, 156 (2d Cir. 1997) (plaintiffs' argument was that ammunitions sales should have been restricted to everyone other than law enforcement and that defendant was responsible for attracting "many types of sadistic, unstable and criminal personalities") (*McCarthy* cited in Mfr. Mem. at 19).

State, 934 P.2d 1018, 1022 (Mont. 1997) ("the intervening criminal act of a third party may be foreseeable . . . in such cases, the factfinder should decide causation in the same manner as in any other intervening causation case") (citation & emphasis om.). Liability may lie where, as here, the third party's actions are foreseeable. *See id*. Further, "in cases involving intervening superseding acts of a criminal or noncriminal nature, 'trial courts must continue to carefully review each fact situation . . . on a case-by-case basis.'" *Samson v. State*, 69 P.3d 1154, 1158 (Mont. 2003) (quoting *Lopez*, 986 P.2d at 1088 [quoting *Estate of Strever*, 924 P.2d 666, 674 (Mont. 1996)]). "The causal issue of intervening criminal or noncriminal acts normally involves questions of fact which are more properly left to the finder of fact for resolution." *Samson*, 69 P.3d at 1158-59 (quoting *Lopez*, as quoting *Strever*; internal quotation marks omitted).

Thus, the Montana Supreme Court repeatedly has recognized that whether the risk was foreseeable to the defendant is a question for the trier of fact, even where, as here, the defendant claims that the acts of a third party constitute an intervening or superseding cause. The *Lopez* court found that a pre-release center for inmates had a duty to protect all persons in the area from an escaped felon. 986 P.2d at 1087-88. *Lopez* emphasizes that in cases involving alleged superseding acts, trial courts must conduct a case-by-case review and that these issues are ordinarily properly "left to the finder of fact for resolution." *Id.* at 1088 (citation omitted). Following *Lopez*, the Montana Supreme Court in *Eklund v. Trost*, 151 P.3d 870, 881 (Mont. 2006), ruled that defendants' intervening

superseding acts theory presented factual scenarios requiring resolution by the factfinder.[45]

Distributor Defendants wrongly contend that *Fisher* requires a particular "relationship" between the parties for the imposition of a duty of care. Dist. Mem. at 24 (citing *Fisher*, 181 P.3d 601). In fact, *Fisher* states that a relationship is only one possible basis for imposition of a duty of care. In addition to "duties based upon relationship," "[a]t the most basic level, we all share the common law duty to exercise the level of care that a reasonable and prudent person would under the same circumstances." 181 P.3d at 606 (citing case example of a railroad having a duty of care). Rather than finding that the plaintiff and defendant's lack of relationship immunized the defendant, the *Fisher* court held that common law and statutory duties were owed by the owner and operator of a semi-truck that hit a highway patrol officer after wreckage-removal company employees detached the semi from a winch. *Id.* at 608 ("We hold that as a matter of law, the Swift driver owed both common law and statutory duties of care to Fisher."). *Fisher* further explains that:

> [I]t is well-settled that neither the specific plaintiff nor the specific injury need be foreseen. . . . In other words, it is not necessary to foresee that [plaintiff] would be injured by the [defendant's] truck sliding across the icy highway as it was being removed from the accident scene, as opposed to, for example, being struck by oncoming traffic.

Id. *See also* § II.C.1 *supra* (discussing *Fisher*). The remainder of the cases cited by Defendants are no more helpful to their argument.[46]

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[45] *See also, e.g.*, *Fisher*, *supra* (genuine issue of material fact as to whether injury to plaintiff, from alleged intervening cause relating to conduct of wreckage-removal company, was foreseeable to driver of defendant's semi-truck trailer, precluded summary judgment for defendant).

[46] For example, Defendants misplace reliance on *Poole v. Poole*, 1 P.3d 936, 441 (Mont. 2000) (cited at Mfr. Mem. at 17; Dist. Mem. at 23), wherein the court decided that the injury was unforeseeable "[b]ased

A growing body of decisions in opioid litigation, penned by trial courts from coast to coast, have rejected these Defendants' various theories as to why they cannot be sued for negligence. Most recently, Purdue lost the argument that New Hampshire's negligent misrepresentation claim must be dismissed because it allegedly did not justifiably rely on statements made or attributable to Purdue. *New Hampshire v. Purdue Pharma Inc., et al.*, Order, No. 217-2017-CV-00402 (Sup. Ct. N.H. Sept. 18, 2018), at 29-30 (Exhibit 1, attached hereto). This decision explains that the United States Supreme Court and Restatement allow plaintiffs directly injured by a misrepresentation to recover even though it was a third party who relied on it. *Id*. Specifically, the Supreme Court identified "the long line of cases in which courts have permitted a plaintiff directly injured by a fraudulent misrepresentation to recover even though it was a third party, and not the plaintiff, who relied on the defendant's misrepresentation." *Bridge v. Phoenix Bond & Indem. Co*., 553 U.S. 639, 656 (2008) (citing Restatement (Second) of Torts §§ 435A, 548A, 870).

In the *In re Opioid Litigation* pending in New York, the court rejected the manufacturer defendants' attempts to blame third parties, deny foreseeability, and draw an analogy to cases where gun manufacturers prevailed. *See In re Opioid Litigation*, No. 400000/2017, 2018 WL 3115102, at *26 (N.Y. Sup. Ct. June 18, 2018). The court found that the New York Counties had both alleged facts sufficient to support the existence of a duty of care and a duty not to deceive. *Id*. The opioid defendants had knowledge of the addictive nature of their products, which they did not disclose. *Id*. The pleadings

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on the[] undisputed facts" that had been established in sworn testimony, including several admissions by the plaintiff contradicting her breach of duty theory.

adequately illustrated that the expectations of plaintiffs, and of society, would require different behavior. *Id.*

More recently, the *In re Opioid Litigation* court rejected similar arguments made by distributor defendants. *In re Opioid Litigation*, No. 400000/2017 (N.Y. Sup. Ct. July 17, 2018), at 19 (filed as Exhibit 4 hereto). The court rejected the defendants' argument that they owed no duty, finding that the defendants' arguments that they lack control and knowledge were inappropriate for resolution in a motion to dismiss. *Id*. The court also found that the Counties adequately pleaded duties owed, including a duty not to fill suspicious orders, a separate duty not to deceive, and a duty under the concerted action theory. *Id*. at 19-20.

In *West Virg. ex rel. Morrisey v. AmerisourceBergen Drug Corp.*, C.A. No. 12-C-141, 2014 WL 12814021 (Boone Cty. Cir. Ct., W. Va. Dec. 12, 2014) [filed in 1:17-md-02804-DAP, Doc. # 654-2], the trial court rejected the opioid distributors' intervening cause argument, reasoning that these defendants were unable to show that "any 'intervening cause' constitutes a new effective cause and operates independently of any other act, making it and it only, the proximate cause of the injury." *Id*. at 23 ¶ 70 [PageID # 15902] (citation omitted). The Court further explained its decision to deny the opioid distributors' motions to dismiss:

> The Court concludes that if it was foreseeable that Defendants' acts and omissions, in failing to provide effective controls against the diversion of controlled substances and design, and in failing to operate a system that discloses suspicious orders of controlled substances contributes to the prescription drug abuse epidemic in West Virginia, then Defendants' alleged actions constitute a proximate cause, a jury may conclude from the State's allegations that Defendants' alleged actions were a substantial contributing factor to the harm and damages alleged by the State in this case.

Id. at 24 ¶ 73 [PageID # 15903]. *See also West Virg. ex rel. Morrisey v. AmerisourceBergen Drug Corp.*, Order Denying Motion to Dismiss, No. 12-C-140 (Boone Cty. Cir. Ct., W. Va. April 17, 2015) [filed in 1:17-md-02804-DAP, Doc. # 580-7, PageID ## 14399-14400], at 21-22 ¶¶ 70-73 (also rejecting intervening cause arguments as basis for motion to dismiss).

The United States District Court for the Western District of Washington rejected Purdue's similar arguments attempting to blame third parties, and deny a "relationship." *City of Everett v. Purdue Pharma L.P*., No. C17-209RSM, 2017 WL 4236062, at *3-4 (W.D. Wash. Sept. 25, 2017). The court found that the City of Everett had "adequately pled that Purdue engaged in an affirmative act which created or exposed Everett to a high degree of risk of harm," and that Everett's theory of liability was viable according to the Restatement (Second) of Torts § 302B. *Id*. at *4.

In other litigation in Washington state, the trial court denied Purdue's motion to dismiss the State's case, finding that, "[r]egarding negligence, the Court finds that the State has pled facts from which reasonable inferences can be drawn that Purdue had a duty of care and that it violated that duty of care. Likewise, the State has pled sufficient facts to establish that Purdue's violation of the duty of care resulted in foreseeable harm," namely the addiction of many Washingtonians to opioids. *Washington v. Purdue Pharma L.P. et al.*, Order, No. 17-2-25505-O SEA (King Cty. Sup. Ct., Wash. May 14, 2018), at 3-4 ¶ 11 [filed in 1:17-md-02804-DAP, Doc. #654-3, PageID 15922-23].

The State of Alaska also succeeded in sustaining its negligence pleadings against a challenge by Purdue. *See State of Alaska v. Purdue Pharma L.P. et al.*, Order, No. 3AN-17-09966CI (3d Jud. Dist., Alaska July 12, 2018), at 10 (filed as Exhibit 3 hereto).

Specifically, the court found that Alaska had adequately pleaded that "Purdue had a duty to the State and its residents: (1) to exercise due care in the advertising, marketing, promotion, and sale of opioid drugs; (2) not to make false, misleading, or deceptive statements about opioids and treatment for chronic pain; and (3) to report suspicious prescribers." *Id*.

b. Plaintiff Does Not Seek To Enforce Statutory Duties.

Defendants take issue with the fact that the Tribe's negligence claim includes citations to federal and state statutes and regulations relevant to defining the standard of care. *See* Mfr. Mem. at 31-33; Dist. Mem. at 22; Pharm. Mem. at 9-11. Relatedly, Defendants contend that the Tribe's negligence count should be dismissed because the Tribe allegedly must establish a private right of action in order to plead negligence. *See* Dist. Mem. at 20-21; Pharm. Mem. at 10. These arguments mistake both the FAC and Montana law.

The Tribe does not contend that the cited enactments and regulations create a private cause of action that the Tribe is enforcing here. As discussed above, the duty that gives rise to Defendants' liability exists under Montana common law. The statutes and regulations Plaintiff cites are, however, relevant to the standard of care to be applied in determining whether Defendants have breached their common law duties. Plaintiff's claims nonetheless exist independently of the statutes and regulations. Defendants have failed to cite any apposite decision in which a negligence count was dismissed at the pleadings stage because it included citations to statutes and regulations defining the standard of care breached by Defendants.

The Tribe also pleads the elements of negligence *per se*. "Under Montana law, it is well established that a duty may arise from a statutorily imposed obligation." *Prindel v.*

Ravalli Cty., 133 P.3d 165, 175 (Mont. 2006) (collecting cases). Here, Plaintiff alleges that Defendants violated the public safety statutes and regulations, (FAC ¶¶ 1013, 1016-22); the Plaintiff is within the class intended to be protected by the public safety statutes and regulations, (*id*. at ¶¶ 1015, 1021); the Plaintiff's injuries are of the sort the statute was enacted to prevent, (*id*. at ¶ 1021); and, the public safety statutes and regulations were intended to regulate members of Defendants' class, (*id*. at ¶ 1016); *accord* Dist. Mem. at 22 (listing elements). Violations of the statutes and regulations thus may operate in either one of two ways, either as evidence of breach of the standard of care or, in the case of negligence *per se*, as *conclusive* evidence of such a breach.

Directly contrary to Defendants' argument, a statute may define the standard of care in a Montana negligence action without providing for civil liability. *See Nehring v. LaCounte*, 712 P.2d 1329, 1333-34 (Mont. 1986) ("Where the statute does not provide for civil liability, the decision to adopt the statute as defining a standard is a judicial one.") (citing Restatement (Second) of Torts § 286 comment d; further citation omitted), *superseded on other grounds by enactment of Dram Shop Act.* A long line of Montana authority finds that creating a private right of action is not a *sine qua non* for imposing a duty of care for purposes of negligence. Specifically, the Montana Supreme Court repeatedly has recognized that statutes that do not create a private right of action can dictate the operative duty in a negligence action. *See, e.g.*, *Fisher*, 181 P.3d at 607 ("each of these three statutes [MONT. CODE ANN. §§ 61-8-302, 61-8-303, 61-8-346] imposed duties of care"); *Eklund*, 151 P.3d at 880 (recognizing that MONT. CODE ANN. § 61-8-107 creates a duty of care); *Prindel*, 133 P.3d at 175-76 (collecting cases in support of proposition that statutorily imposed obligations may impose a duty under well-

established Montana law and citing MONT. CODE ANN. §§ 7-32-2205, 7-32-2208, neither of which expressly creates a private right of action); *Jackson v. State*, 956 P.2d 35, 49, 51 (Mont. 1998) (noting that "[i]t is axiomatic that applicable statutes may create a duty in a negligence action," and concluding that adoption statute at issue imposed a duty) (citation omitted); *Gibby v. Noranda Minerals Corp*., 905 P.2d 126, 130-31 (Mont. 1995) (defendant owner had "a nondelegable duty under Montana's Safe Place to Work statute, § 50-71-201, MCA, to provide [plaintiff] with a safe working environment").

A statute that is enforceable through convictions and government penalties can define the duty owed in a negligence action. For example, in *Fisher*, 181 P.3d at 607, the Montana Supreme Court expressly recognized a duty of care based on Montana Code Section 61-8-302, which is punishable by misdemeanor convictions and penalty fines. *See* MONT. CODE ANN. § 61-8-302(2) ("A person who is convicted of the offense of careless driving is subject to the penalties provided in 61-8-711 or 61-8-716."); *accord* MONT. CODE ANN. §§ 61-8-711, 61-8-716 (penalties include misdemeanor convictions, fines, potential incarceration). In *Fisher*, as here, the plaintiff was not attempting to stand in the shoes of the government and collect a fine.[47]

The Manufacturer and Distributor Defendants misplace reliance on *Doyle v. Clark*, 254 P.3d 570 (Mont. 2011), *superseded on other grounds*, as stated in *Peterson-Tuell v. First Student Transp., LLC*, 339 P.3d 16, 22 (Mont. 2014).[48] *Doyle* found that "a private individual" cannot recover on the basis of a statutory violation unless the statute "allows a private right of action." 254 P.3d at 577 (citing case discussed below). But in

[47] *Contrast also Faust v. Utility Solutions, LLC*, 173 P.3d 1183, 1187 (Mont. 2007) (private parties not allowed to enforce civil penalty provisions of Water Use Act) (case cited at Pharm. Mem. at 10).

[48] *Doyle* is cited at the Mfr. Mem. at 31, 33, without a disclosure that the decision is superseded in part.

light of the body of case law cited, this cannot mean what Defendants think it means. Indeed, Defendants' construction is directly contrary to the holding of *Wombold v. Assoc. Fin. Serv. Co.*, 104 P.3d 1080, 1085-87 ¶¶ 32-47 (Mont. 2004), *overruled on other grounds, Essex Ins. Co. v. Moose's Saloon, Inc.*, 166 P.3d 451 (Mont. 2007), cited by the *Doyle* court. In *Wombold*, the court rejected the argument that a statute "does not allow" for a private right of action unless it expressly creates one. The statute in *Wombold* specifically provided that "'[a]ll powers and duties of regulation and supervision conferred by this chapter are vested in the department." 104 P.3d at 1085. Nonetheless, the *Wombold* court found that the statute allowed an implied private right of action for borrowers to file suit against lenders, without otherwise establishing the elements of negligence.

A distinguishable example of when a statute does not "allow" an action appears in *Johnson v. Columbia Falls Aluminum Co., LLC*, No. DA 08-0358, 2009 WL 865308 (Mont. March 31, 2009) (unpublished disposition at 213 P.3d 789; not precedent).[49] There, an employee brought a wrongful discharge action, and the court rejected the argument that the employee could bring a negligence *per se* claim action under the Medical Marijuana Act because the Act "specifically provides that it cannot be construed to require employers 'to accommodate the medical use of marijuana in any workplace.'" *Johnson*, 2009 WL 865308 at *2 (quoting MONT. CODE ANN. § 50-46-205(2)(b) (repealed)). Thus, the *Johnson* plaintiff's negligence *per se* theory was directly contradicted by the statutory language. Together, *Wombold* and *Johnson* show that such

[49] In citing *Johnson*, Distributor Defendants fail to inform the Court that the decision by its terms "shall not be cited as precedent." 2009 WL 865308 at *1; *accord* Dist. Mem., 21.

an express contradiction in the statutory language is required before a claim based on negligence *per se* will be prohibited. Of course, there is no such contradiction here.

Defendants suggest that the statutes and regulations cannot provide the relevant standard of care because they do not declare "protection to the Tribes for their asserted injuries." Mfr. Mem. at 32; *see also* Dist. Mem. at 22 ("enacted to protect an Indian tribe"). But it is clear that these laws were intended to protect *inter alia* the health and welfare of the Tribe. The FAC cites a codified section of the federal Controlled Substances Act (CSA) and a federal regulation promulgated pursuant to the CSA. FAC ¶¶ 1009, 1021. The FAC also cites state law requiring compliance with federal law.[50] The federal CSA was enacted because it was deemed "necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801. This is sufficient under Montana law. *Compare, e.g., Prindel*, 133 P.3d at 176-77 ("the statutory provisions quoted above evidence the existence of the Jail's duty to take Russell into custody for the protection of the surrounding public"). *See also West Virg. ex rel. Morrisey v. AmerisourceBergen Drug Corp.*, Order Denying Motions to Dismiss, No. 12-C-140 (Boone Cty. Cir. Ct., W. Va. April 17, 2015) [filed in No. 1:17-md-02804-DAP, Doc. # 580-7, PageID # 14392], at 13 ¶ 49 ("the State and its agencies are Plaintiffs in this case as representatives of the State and the public, for whose benefit the statute and

[50] The FAC cites a provision of the CSA, a federal CSA regulation, the Montana statute requiring compliance with federal law, and the Montana regulation. *See* FAC ¶¶ 1009, 1021. The Montana regulation broadly incorporates any applicable federal or state requirement; nonetheless, the regulation clearly focuses on compliance with the CSA – not the FDCA. *See* Mont. Admin. R. 24.174.1201(6) ("Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations. Wholesale drug distributors who deal in controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local, and DEA regulations."). However, Manufacturer Defendants cite cases interpreting the FDCA, not the CSA. *See* Mfr. Mem. at 32. These cases are inapposite.

accompanying regulations [requiring effective controls to guard against prescription drug diversion were] enacted").

The Manufacturer Defendants finally contend that a claim "based on the violation of a regulation" allegedly fails as a matter of law. Mfr. Mem. at 33. First, the Sixth Claim for Relief does not rely on the regulations cited, but rather expressly cites to the source statutes that the regulations are implementing. *See* FAC ¶¶ 1009-10, 1021. Therefore, the regulations serve as relevant interpretations of the statutes rather than a stand-alone basis for the standard of care owed. Second, contrary to Defendants' argument, the Montana Supreme Court has explained that duty in a negligence claim can be established by an agreement, rules and regulations, statute, or common law. *See Rookhuizen v. Blain's Mobile Home Court, Inc*., 767 P.2d 1331, 1333 (Mont. 1989). Similarly, the United States Supreme Court has observed that, "[t]he violation of federal statutes and regulations is commonly given negligence *per se* effect in state tort proceedings." *Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg*., 545 U.S. 308, 318-19 (2005) (quot. mark, cit. & not. om.). Consistently, the Restatement does not distinguish between legislative enactments or administrative regulations when discussing the duty of care in negligence actions.[51] Notably, the Montana Supreme Court has cited the Restatement

[51] *See* Restatement (Second) of Torts § 286 (1965) (discussing "legislative enactment or an administrative regulation" as standard of conduct of a reasonable man); *id*. at § 288B (1965) ("(1) The unexcused violation of a legislative enactment or an administrative regulation which is adopted by the court as defining the standard of conduct of a reasonable man, is negligence in itself. (2) The unexcused violation of an enactment or regulation which is not so adopted may be relevant evidence bearing on the issue of negligent conduct."); *cf.* Restatement (Third) of Torts: Phys. & Emot. Harm § 14 cmt. a (2010) (negligence *per se* "most frequently applies to statutes adopted by state legislatures, but equally applies to regulations adopted by state administrative bodies, ordinances adopted by local councils, and federal statutes as well as regulations promulgated by federal agencies").

with approval repeatedly,[52] including citing the comments to one of the Restatement sections that does not distinguish between statutes and regulations.[53]

2. Defendants Cannot Win Rule 12(b)(6) Dismissal by Denying the Operative Facts.

"Questions of negligence typically involve questions of fact and are generally not suited for summary judgment" – much less for dismissal on the pleadings. *See Newman v. Lichfield*, 272 P.3d 625, at 633 (Mont. 2012) (citation omitted). Questions of negligence ordinarily "are better left for jury determination at trial." *Harrington v. Crystal Bar, Inc.*, 306 P.3d 342, 344 (Mont. 2013) (cit. & quot. om.); *see also, e.g., Prindel*, 133 P.3d 165 (summary judgment for defendant reversed; court found fact issue existed as to whether stabbing was so unforeseeable as to sever chain of causation).

While the intensely fact-based nature of negligence causes of action undercut all Defendants' negligence arguments, it is particularly fatal to the Distributor Defendants' claim that they allegedly did not breach a duty as a matter of law. Distributors' Mem. at 24-25. Far from supporting Distributors' argument, *Hatch v. Dept. of Highways*, 887 P.2d 729, 732 (Mont. 1994), was decided at the summary judgment stage based on deposition testimony, and even then the court declined to decide whether a duty had been breached.

3. Plaintiff Has Properly Pleaded Negligent Misrepresentation.

Under Montana law, it is "not necessary that the negligent misrepresentation constitute constructive fraud, nor actual fraud." *Bottrell v. American Bank*, 773 P.2d 694, 706 (Mont. 1989). "'Negligent misrepresentation has a lesser standard of proof than fraud. Rather than requiring an intent to misrepresent, it requires a showing of a failure to

[52] *See, e.g., Peterson v. Eichhorn*, 189 P.3d 615, 620 (Mont. 2008) (cataloguing several specific sections of the Restatement that the Montana Supreme Court has adopted); *Sunburst Sch. Dist. No. 2 v. Texaco, Inc.*, 165 P.3d 1079, 1087 (Mont. 2007) (citing and adopting Restatement (Second) of Torts § 929 cmt. b).

[53] *See Nehring, supra*, 712 P.2d at 1334 (citing Restatement (Second) of Torts § 286 comment d).

use reasonable care or competence in obtaining or communicating the information.'" *Hayes v. AMCO Ins. Co.*, No. CV 11-137-M-DWM, 2012 WL 5354553, at *4 (D. Mont. Oct. 29, 2012) (quoting *Barrett v. Holland & Hart*, 845 P.2d 714, 717 (Mont 1992)). Therefore, Montana law recognizes a clear distinction between fraud on the one hand, and negligent misrepresentation on the other.

A Montana cause of action for negligent misrepresentation is subject to the pleading standards of Rule 8 rather than Rule 9(b). *E.g., W. Sec. Bank v. Eide Bailly LLP*, 249 P.3d 35, 46-47 (Mont. 2010) (analyzing fraudulent misrepresentation claim pursuant to M.R.C.P. 9(b), but not applying Rule 9(b) in subsequent discussion of negligent misrepresentation claim); *Fischer v. Ocwen Loan Servicing, LLC*, No. CV-14-94-BLG-SPW-CSO, 2014 WL 6685987, at *9 (D. Mont. Nov. 25, 2014), *report and recommendation adopted*, No. CV 14-94-BLG-SPW-CSO, 2014 WL 11498231 (D. Mont. Dec. 11, 2014) (applying Rule 8(a)(2)'s requirement of a short and plain statement to Count VIII, negligent misrepresentation and negligence); *see also Koontz v. Bank of Am., N.A.*, No. CV 15-108-M-DLC, 2016 WL 595290 (D. Mont. Feb. 12, 2016) (the fraud count (VI) is analyzed under Rule 9(b), but there is no analysis of the negligent misrepresentation count (II) under Rule 9(b)).[54] Thus as an initial matter, Manufacturer

[54] *See also CNH Am. LLC v. Int'l Union, United Auto., Aerospace and Agric. Implement Workers of Am.*, 645 F.3d 785, 794 (6th Cir. 2011) ("[s]o long as the [ ] [plaintiff's] allegations are 'plausible,'" a negligent-misrepresentation claim governed by Wisconsin law could survive under "the modest notice-pleading requirements of Civil Rule 8(a)."); *Tricontinental Indus., Ltd. v. PricewaterhouseCoopers, LLP*, 475 F.3d 824, 833 (7th Cir. 2007) (negligent misrepresentation under Illinois law was "*not* governed by the heightened pleading standard of Rule 9(b)"); *Gen. Elec. Capital Corp. v. Posey*, 415 F.3d 391, 394-96 & n.2 (5th Cir. 2005) (concluding that negligent representation claim needs only to satisfy notice pleading standard of Rule 8(a)) (citing 2 James Wm. Moore *et al*., Moore's Federal Practice § 9.03 [1] [d], at 9–21 (3d ed. 2005)); *Baltimore County v. Cigna Healthcare*, 238 F. App'x 914, 921 (4th Cir. 2007) ("a claim of negligent misrepresentation under Maryland law does not contain an essential showing of fraud and thus the heightened pleading requirements of Rule 9(b) do not apply") (citing *Tricontinental Indus*. and *Gen. Elec. Capital Corp*.); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 159 F. Supp. 3d 898, 927 (N.D. Ill. 2016) ("In contrast to a claim sounding in fraud, Rule 9(b)'s strictures do not apply to claims of negligent misrepresentation.") (citing *Tricontinental*); *Carl Kelley*

and Pharmacy Defendants err in asserting that the negligent misrepresentation portion of the Sixth Claim for Relief must be treated as fraud and pleaded with particularity. *See* Mfr. Mem. at 55; Pharm. Mem. at 11-12. Here, the Complaint's Sixth Claim for Negligence and Negligent Misrepresentation does not include any pleadings that sound in fraud. This is not a case in which fraud and negligent misrepresentation have been conflated. Specifically, common law fraud is pleaded against the Manufacturer Defendants only and not against the Distributor Defendants or Pharmacy Defendants, yet all Defendants are named in the Negligence and Negligent Misrepresentation claim. The Tribe is not attempting to sneak in fraud allegations against the Distributor or Pharmacy Defendants under the guise of negligent misrepresentation. Thus, there is no justification for applying Rule 9(b) here.

Unlike the Manufacturer and Pharmacy Defendants, Distributor Defendants do not misstate the pleading standard for negligent misrepresentation. Instead, Distributor Defendants argue that the Manufacturers made the misrepresentations, that the Tribe allegedly fails to "identify even a single misrepresentation by Distributors" and therefore fails to allege untrue statements or reliance, and that the Tribe fails to allege injury resulting from reliance. Dist. Mem. at 25-26. Pharmacy Defendants allege that the Tribe fails to plead representations, intent to induce reliance, reliance, or damages. Pharm. Mem. at 11. These denials overlook the Tribe's pleadings.

The FAC pleads Defendants' material misstatements (FAC ¶¶ 1039-1041), intent to induce reliance (*id.* at ¶¶ 1042-1043), rightful, reasonable, and justifiable reliance (*id.* at ¶¶ 1044, 1046), and resulting pecuniary losses and damages (*id*. at ¶¶ 1045, 1047). The

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Const. LLC v. Danco Techs., 656 F. Supp. 2d 1323, 1346 (D. N.M. 2009) ("[U]nlike with fraudulent misrepresentation, rule 8's notice pleading standard governs [negligent misrepresentations].").

misstatements constituted Defendants' portrayal of themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy their minimum, legally-required obligations to report suspicious orders (*id*. at ¶ 1039). The Sixth Claim for relief also incorporated by reference the prior pleadings of Defendants' misrepresentations (*see id*.).

Defendants are on notice of the allegations against them. For example, the Tribe explains that, "Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens." FAC ¶ 574. Twelve paragraphs in the FAC describe misrepresentations in this regard, including several quotes of Defendants' untrue representations of fact. *Id*. at ¶¶ 574-585. *See also id*. at ¶ 616 (CVS acknowledgement of legal obligation); ¶ 726 (explaining Defendants' concealment of "lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied"); *id*. ("broad promises to change their ways"), ¶¶ 799-827 (description of supply chain enterprise). Distributor Defendants, as part of the supply chain enterprise, disseminated the false and misleading statements that 1) the quotas for prescription opioids should be increased; 2) they were complying with their obligations to maintain effective controls against diversion of their prescription opioids; 3) they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids; 4) they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and 5) they did not have the capability to identify suspicious orders of controlled substances. *Id.* at ¶ 806.

In short, the Sixth Claim for Relief, sounding in Negligence and Negligent Misrepresentation, places Defendants on ample notice.

E. Plaintiff Has Properly Pleaded an Unjust Enrichment Claim.

Defendants seek to dismiss Plaintiff's claim for unjust enrichment for the same reasons argued elsewhere, and/or because Plaintiff did not allege the required elements under Montana law. Dist. Mem. at 26-27; Mfr. Mem. at 39-42; Pharm. Mem. at 12-13. Defendants' arguments fail for the reasons advanced in prior briefing and under Montana law. *Summit* Opp. Mem. at 95-99; *Chicago* Opp. Mem. at 41-42.

The elements of an unjust enrichment claim are "(1) defendant received a benefit; (2) defendant knew about or appreciated the benefit; and (3) defendant accepted or retained the benefit under circumstances where it was inequitable for defendant to do so." *Volk v. Goeser*, 367 P.3d 378, 389 (Mont. 2016). Under Montana law, "[u]njust enrichment merely requires proof that a party unjustly gained something of value, regardless of wrongful conduct." *Associated Management Services, Inc. v. Ruff*, 424 P.3d 571, 595 (Mont. 2018). The Eighth Claim for Relief properly pleads these elements.

The Defendants received benefits from the Tribes. As the FAC explains, Defendants' wrongful conduct in selling and distributing opioids causes *inter alia*, increased healthcare service and addiction treatment for opioid users. FAC ¶¶ 1074-1075, 1077, 1985. These costs are part of Defendants' business, yet Defendants are not paying for them: they have externalized these unavoidable costs and imposed them on others.[55] These costs are "not part of the normal and expected costs of a local government's existence." Yet Plaintiff, and other tribes, are paying them. FAC ¶ 1084. By using

[55] Federal and state unjust enrichment jurisprudence recognizes that defendants are unjustly enriched where, as here, a plaintiff must bear the cost of negative externalities that defendants caused. *See* Summit Opp. Mem. at 96-98 (collecting cases, including regarding pollution costs).

Plaintiff to fund Defendants' negative externalities (the cost of the harms caused by their wrongful practices), Defendants knowingly saved on expenses, thereby allowing them to sell and distribute more opioids, and make more money, than if they had internalized the actual cost of their activities. *Id*. at ¶¶ 1078-1085. Contrary to Defendants' contention, these economic realities are not conclusory allegations. Defendants have thereby received a benefit unjustly financed by the Plaintiff.

Defendants rely on *Montana Petroleum Release Compensation Board v. Capitol Indem. Co.*, 137 P.3d 522, 529 (Mont. 2006) for the tautology that "one cannot be unjustly enriched by failing to pay a debt one does not owe." But this dictum occurs in a convoluted subrogation case involving successor and extinct entities in a decades-long groundwater remediation case whose facts cannot be stretched to apply to the conduct here.

Defendants' claim that Montana has rejected efforts to expand unjust enrichment claims is likewise incorrect. To the contrary: Montana recognizes that "the concept of unjust enrichment plays an important role as a tool of equity" that was "developed to remedy injustice when other areas of the law could not," and, thus, "must remain a flexible and workable doctrine." *Northern Cheyenne Tribe v. Roman Catholic Church ex rel. Dioceses of Great Falls/Billings*, 296 P.3d 450, 457 (Mont. 2013) (citation omitted).[56]

The cases cited by the Defendants do not fit this case. *Oregon Laborers-Employers Health and Welfare Trust Fund v. Phillip Morris, Inc.*, 185 F.3d 957 (9th Cir

[56] *Darty v. Grauman*, 419 P.3d 116, 120 (Mont. 2018) merely held that the decedent was free to change his mind and decide not to transfer the Ameriprise accounts, thus, the plaintiff could not establish that the TOD Beneficiaries accepted or retained the proceeds from the Ameriprise accounts under inequitable circumstances.

1999) involved employee health and welfare benefit plans filing suit against tobacco companies seeking to recover expenditures incurred for medical assistance due to participants' and beneficiaries' tobacco use. The *Oregon* plaintiffs merely pled that they conferred a "benefit" on defendants by paying the medical bills of the smokers. *Id.* at 968-69. The court applied Oregon law, finding that because the plaintiffs had an independent obligation to pay the smokers' medical expenses, they could not maintain an action against defendants as incidental beneficiaries. In this case, Montana law applies and the FAC expressly alleges that the Defendants were more than incidentally benefitted. *Perry v. Am. Tobacco Co.*, 324 F.3d 845 (6th Cir. 2003) involved insureds under a group health insurance policy who brought a putative class action against tobacco manufacturers, alleging that they paid increased insurance premiums due to the presence of smokers in the insurance pool. The court found that the payment of smokers' medical costs by a third party did not enrich the defendants. *Id.* at 851. In this case, Plaintiff has clearly pled that the Defendants were enriched. In *Ashley County, Ark. v. Pfizer, Inc.*, 552 F.3d 659, 665 (8th Cir. 2009), plaintiff claimed defendants were unjustly enriched when methamphetamine cooks purchased the Defendants' products for use in the illegal manufacture of methamphetamine. Arkansas law requires that "it is not enough, however, to establish a benefit received by another party. 'There must also be some operative act, intent, or situation to make the enrichment unjust and compensable.'" *Id.* Under Arkansas law, "unjust enrichment is based on an implied contract theory of recovery," and courts "will only imply a promise to pay for services where they were rendered in such circumstances as authorized the party performing them to entertain a reasonable expectation of their payment by the party beneficiary." *Id.* at 666. This is not the law of

Montana. In *City of Miami v. Bank of America Corp.*, 800 F.3d 1262, 1288, 1289 (11th Cir 2015), *vacated and remanded by Bank of America Corp. v. City of Miami*, 137 S. Ct. 1296 (2017), based on Florida's substantive law, the court found that at least one Florida case suggested that a municipality could not recover expenditures without express statutory authorization, which Miami had never alleged.[57]

Distributor Defendants assert that unjust enrichment is entirely derivative of other claims that the Distributors contend are deficient, and should be dismissed along with them. But here Plaintiff has pleaded valid claims. Even if those claims were to fail, the improper conduct underlying them would still support a claim for unjust enrichment under Montana law, which deploys the claim as a vital "tool of equity" to remedy injustice when other areas of the law cannot. In Montana, unjust enrichment is not derivative or disfavored; it is a flexible and workable doctrine that can be applied with full force to restore the economic balance that Defendants' conduct has disrupted.

F. Plaintiff Has Properly Pleaded a Claim for Civil Conspiracy.

Defendants contend that Plaintiff has not properly pleaded a claim for civil conspiracy. Mfr. Mem. at 67-68; Dist. Mem. at 28-29; Pharm. Mem. at 13-15. Plaintiff incorporates the briefing in Summit County and the City of Chicago. *Summit* Opp. Mem. at 99-105; *Chicago* Opp. Mem. at 39-41; *Chicago* Consol. Opp. Mem. at 23-25. Defendants' arguments that the underlying tort claims fail and that the Tribe has failed to plead any underlying unlawful acts[58] (Mfr. Mem. at 67-68; Dist. Mem. at 29, Pharm.

[57] *See* 800 F.3d at 1288, 1289 (citing *Penelas v. Arms Tech., Inc.*, No. 99-1941 CA-06, 1999 WL 1204353, at *2 (Fla. Cir. Ct. Dec. 13, 1999), *aff'd*, 778 So.2d 1042 (Fla. Dist. Ct. App. 2001)).

[58] Manufacturer Defendants cite to three out of jurisdiction cases as support for the unremarkable position that Plaintiff must allege that the Defendants had knowledge of the intended harm at the beginning of the conspiracy and that parties cannot negligently agree to participate in a conspiracy. The FAC is replete with evidence that the closed distribution system was set up to prevent diversion. Defendants do not allege, nor

Mem. at 15) are unfounded for the reasons catalogued above and in the Summit County and Chicago briefing. *Summit* Opp. Mem. at 100; *Chicago* Consol. Opp. Mem. at 23-25, *Chicago* Opp. Mem. at 39-41.

Under Montana law, "[a] valid conspiracy claim requires that each of the following elements be established: '(1) two or more [conspiring] persons …; (2) an object to be accomplished; (3) a meeting of the minds on the object or course of action; (4) one or more unlawful overt acts; and (5) damages as the proximate result therewith.'" *Sullivan v. Cherewick*, 391 P.3d 62, 68 (Mont. 2017) (quoting *Schumacker v. Meridian Oil Co.*, 956 P.2d 1370, 1373 (Mont. 1998)). As noted above, the pleading standards of Rule 8 apply to this claim. *See* above, § II.D.

Montana law recognizes that, "[b]ecause direct evidence of the meeting of the minds is typically in the possession and control of the alleged conspirators and, therefore, difficult-if not impossible-to obtain, we hold that circumstantial evidence may be used to establish the meeting of the minds element of a civil conspiracy." *Schumacker*, 956 P.2d at 1373-74.[59] Agreements may be inferred from circumstantial evidence. *Chicago* Opp. Mem. at 39-41.

The Defendants contend that the FAC fails to set forth sufficient facts in relation to the elements of "meeting of the minds"; "unlawful overt acts"; and "proximate cause."

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can they, that foreseeable harms would result from illegal diversion. The FAC does not allege that the Defendants negligently or unknowingly entered into a conspiracy. The FAC sets forth sufficient facts that the Defendants knowingly engaged in a civil conspiracy to unlawfully and tortuously market and distribute opioids. To the extent that the Defendants acted with negligence in furtherance of such conspiracy, such negligence can constitute an unlawful act.

[59] *Schumacker* noted that "other states have allowed the use of circumstantial evidence to establish the meeting of the minds element of a civil conspiracy due to the difficulty in obtaining direct evidence on that element." *Id.* at 1373 (citing *Four R Cattle Co. v. Mullins*, 570 N.W.2d 813, 818 (Neb. 1997) (citation omitted); *Adam v. Mt. Pleasant Bank & Trust Co.*, 387 N.W.2d 771, 773 (Iowa 1986) (citation omitted); *Beverly v. McCullick*, 505 P.2d 624, 633 (Kan. 1973) (citation omitted); and *Shows v. Silver Shield Mining and Milling Company*, 375 P.2d 522, 524 (Colo. 1962)).

The Defendants are wrong. The FAC contains numerous paragraphs setting forth the distribution combination as to all Defendants. FAC ¶¶ 586-635, 714-720, 856-887, 1087-1106. Defendants engaged in a civil conspiracy to unlawfully and tortiously market and distribute opioids, including through failure to abide by their prevention and monitoring duties, misrepresentation, and fraud. FAC ¶¶ 1088-1095. Here, "each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do." FAC ¶ 1099. Defendants' combined efforts to inflate the opioid quotas – in contravention of their legal duties – are detailed in the FAC. FAC ¶¶ 489, 513-572. Plaintiff further describes how Defendants, through their participation in trade associations, worked together to mislead the public regarding Defendants' commitment to complying with their legal obligations and safeguarding against diversion. FAC ¶¶ 578-79, 581. As additional examples of the raft of conduct chronicled in the FAC, the Defendant co-conspirators deliberately concealed their knowledge of each other's wrongdoing. FAC ¶¶ 723-25. These detailed allegations exceed far beyond the parallel acts consistent with marketplace competition at issue in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). *See also Summit* Opp. Mem. at 102-05 (listing additional allegations also contained in Blackfeet Tribe's FAC).

Finally, the Pharmacy Defendants repeat the inaccurate argument that the FAC omits allegations against them and solely pertains to the Marketing Defendants. *See* Pharm. Mem. at 15. This contention ignores allegations specific to the pharmacies and their wrongdoing (*e.g.*, *inter alia*, FAC ¶¶ 494, 578, 586-635), and allegations including the pharmacies (*e.g.*, *inter alia* FAC ¶¶ 477, 480-484, 515-516, 541-544, 578-579, 714-

720, 1088-1095). Among other things, the pharmacies participated with the other Defendants in the financially incentivized, improper exchange of information. FAC ¶¶ 515, 586. The national pharmacy chains "were keenly aware of the oversupply" and in breach of mandatory duties "participate[d] in the oversupply" for profit and provided the other Defendants with data. FAC ¶¶ 586, 589. The Pharmacy Defendants also failed to use data available to them to identify doctors who were writing suspicious orders, even while maintaining extensive data on the opioids that they distributed and dispensed. FAC ¶¶ 589, 602. In short, the FAC includes descriptions of the pharmacies' knowing participation in the exchange of information with other Defendants, and the abdication of mandatory duties, comprising the wrongful distribution of dangerous drugs on a massive scale nationally, and specifically within the Blackfeet Geographic Region.

Defendants' arguments pertaining to proximate cause fail for all the reasons set forth in § II.C., *supra*, and the Summit County and Chicago briefing. *Summit* Opp. Mem. at 11-16; and *Chicago* Opp. Mem. at 26-29.

IV. PLAINTIFF PROPERLY PLEADS ITS RICO CLAIMS

As this Court is aware, the Manufacturer and Distributor Defendants[60] previously filed motions to dismiss the Complaint in *Summit County*. That briefing provided the Court with well over 100 pages devoted to federal (and state) RICO claims. Manufacturer[61] and Distributor Defendants move to dismiss the Plaintiff's RICO claims

[60] For purposes of this section only, references to Manufacturer Defendants and Distributor Defendants refer to the Manufacturer and Distributor Defendants, including those Manufacturers who manufactured generic opioids (also referred to as Generic Manufacturers), named as defendants in the RICO claims in the FCA, Claims for Relief 1-2.

[61] The Manufacturer Defendants' attempt to argue dismissal by chart is generally a disfavored tactic in federal court. *See, e.g., In re Chrysler-Dodge-Jeep Ecodiesel Marketing, Sales Practices, and Products Liability Litigation*, 295 F. Supp. 3d 927, 1015 (N.D. Cal. 2018) ("[T]he Court takes note that Defendants have provided a joint appendix . . . and . . . rejects Defendants' attempt to make argument via the joint

by, with few exceptions, regurgitating the arguments asserted in *Summit County*.[62] As in *Summit County*, the Manufacturer and Distributor Defendants now argue that Plaintiff: (1) lacks standing because it lacks injuries to business or property; (2) cannot establish the RICO enterprises; (3) has not adequately alleged racketeering activities; and (4) cannot bring RICO claims because they are precluded by the Food, Drug, and Cosmetic Act ("FDCA"). Despite some (minor) new twists, these old argument remain unpersuasive.[63]

Plaintiff has pleaded strong cognizable RICO claims based on its own injuries that it sustained as a commercial participant and to its revenue generating functions. Plaintiff's injuries are premised on a direct causal relationship to the RICO Defendants' racketeering activities. Moreover, Plaintiff has pleaded the formation of the Opioid Marketing and Supply Chain Enterprises, as well as each RICO Defendant's control of and participation in either enterprise. Plaintiff pleaded its RICO claims with the necessary particularity, and established a valid basis for holding the RICO Defendants' liable for their respective conduct of and participation in the Opioid Marketing and/or

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appendix. This Court, like the court in *Counts* [*v. General Motors, LLC*, 237 F. Supp. 3d 572 (E.D. Mich. 2017)], deems those arguments waived."); *see also*, *Counts*, 237 F. Supp. 3d at 593-94 (rejecting "attempt[] to 'raise' certain state-specific arguments by referencing appendices attached to their briefing" and pointing out that the "scattershot effort to raise arguments and defenses by simply citing to dozens, if not hundreds, of state court cases will not be addressed," particularly as the court permitted expanded briefing and a court is not "responsible for combing through appendices in an attempt to *sua sponte* raise and resolve legal arguments which the parties have not briefed").

[62] Much of the Manufacturer and Distributor Defendants' arguments re-argue aspects of their earlier briefs and both defendant groups incorporate their arguments from the earlier *Summit County* briefing by reference. Plaintiff similarly incorporates all arguments related to the RICO claims at issue in *Summit County* and incorporate, by reference, the sections of the *Summit* Opposition filed therein, including but not limed to, Sections I.B., I.C.2., and II.B.1-2.

[63] Defendants also argue that Plaintiff has not pleaded its RICO claim with sufficient particularity and fails to allege proximate cause. Those arguments are addressed above, *See supra* Sections II.C-II.D.

Supply Chain Enterprises. And, finally, Plaintiff's RICO Marketing claims are not precluded by the FDCA.

A. RICO Provides the Appropriate Civil Remedy Under the Circumstances of this Case.

Defendants argue, as they did in their *Summit County* motions, that Plaintiff's claims are not properly cognizable under RICO. These arguments rest on an unreasonably restrictive reading of RICO that contradicts decades of Supreme Court authority and instruction. As argued more fully in the *Summit* Opposition:

> RICO is to be read broadly. This is the lesson not only of Congress' self-consciously expansive language and overall approach, . . . but also of its express admonition that RICO is to "be liberally construed to effectuate its remedial purposes," Pub.L. 91-452, § 904(a), 84 Stat. 947. The statute's "remedial purposes" are nowhere more evident than in the provision of a private action for those injured by racketeering activity.

Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479, 497-98 (1985) (quoting *United States v. Turkette*, 452 U.S. 576, 586-587 (1981) and Organized Crime Control Act of 1970, Pub. L. No. 91-452, § 904(a), 84 Stat. 922, 947).

Congress chose "self-consciously expansive language" for RICO, broadly defined the predicate racketeering acts, and mandated a liberal construction. *Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 563 (6th Cir. 2013) (quoting *Sedima*, 473 U.S. at 498). "[T]he fact that RICO has been applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth." *Id.* (quoting *Sedima*, 473 U.S. at 499 (quoting *Haroco, Inc. v. Am. Nat'l Bank & Trust Co. of Chi.*, 747 F.2d 384, 398 (7th Circ. 1984))). The Supreme Court has consistently applied Civil RICO to new scenarios and a broad array of enterprises, recognizing that "respected" businesses can nonetheless combine and act to violate RICO. In *Sedima*, the Court stated that "Congress wanted to reach both 'legitimate' and 'illegitimate' enterprises," because

"[t]he former enjoy neither an inherent incapacity for criminal activity nor immunity from its consequences." *Sedima*, 473 U.S. at 499.

This principle reaches its zenith with respect to RICO's private right of action, which is intentionally broad and provides flexible concepts of causation. *See, e.g.*, *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 652, 654 (2008). RICO has been employed to hold corporations accountable when they participate in vast illegal enterprises that inflict unprecedented—and disastrous—consequences on society. *See United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in part and vacated in part*, 566 F.3d 1095 (D.C. Cir. 2009). It is, therefore, unsurprising that RICO has been employed to hold pharmaceutical manufacturers liable for using a web of entities to market a dangerous prescription drug for off-label use, deceiving doctors into prescribing it widely and causing insurers to pay for off-label prescriptions. *See In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013). In *Neurontin*, the First Circuit upheld a RICO award of $140 million, finding that the defendants' fraudulent marketing enterprise caused excessive prescriptions, damaging the insurer plaintiff. *Id.* at 33-50.

Plaintiff's RICO claims are equally appropriate and necessary in this litigation. The Manufacturer and Distributor Defendants are businesses engaged in sophisticated, complex, and decades-long fraudulent schemes for economic gain designed to create a captive market of addicted individuals in order to unlawfully profit from opioids sales, and then open the distribution flood gates and knowingly profit from the diversion of suspicious orders. They knowingly externalized foreseeable and inevitable economic

losses from this conduct. Defendants created and profited from a mess they knew and intended that Plaintiff and other public entities would be left to clean up.

The widespread scope and pervasiveness of the RICO Defendants' conduct cannot be overstated. And the injuries sustained by Plaintiff as a sovereign nation are similarly pervasive and widespread. Here, the Opioid Marketing Enterprise—which relied on front groups and key opinion leaders to spread pseudo-science that fostered opioid addiction—rivals the tobacco defendants' enterprise consisting of "formal and informal entities, many with overlapping participants and purposes" in "the largest piece of civil litigation ever brought." *Philip Morris*, 449 F. Supp. 2d at 34, 870. Plaintiff's claim that the Manufacturers created a fraudulent enterprise to get thousands of unwitting physicians to foster widespread dependence on prescription pharmaceuticals is even stronger than the *Neurontin* plaintiff's RICO claims, which were proved by statistical evidence at trial and upheld by the First Circuit on appeal. In the wake of the widespread dependence created by the RICO Marketing Defendants, the RICO Supply Chain Defendants formed the Opioid Supply Chain Enterprise whose members systematically concealed, and refused to report, suspicious orders of prescription opioids so that the flood-gates of unlawful opioids would remain wide open, and annual quotas would increase. Plaintiff's claims are consistent with the purpose and spirit of RICO, and specifically the economic losses civil RICO compensates, punishes and deters. In this equally important case, the RICO claims should proceed.

B. Plaintiff's Injuries Establish RICO Standing.

Both the Manufacturer and Distributor Defendants attempt to dismiss the entirety of Plaintiff's RICO Marketing and Supply Chain claims by arguing that Plaintiff has not sufficiently alleged an injury to its business or property in order to establish standing as a

person. Because the arguments asserted by the Manufacturer and Distributor Defendants largely duplicate their arguments from the *Summit* Motions to Dismiss,[64] those arguments are already well-briefed as they relate to the categories of damages that Plaintiff seeks. To the extent that the Manufacturer and Distributor Defendants assert new arguments, or new authority in support of old positions, those arguments lack merit as more fully explained below.

First, contrary to the Distributors' position, Plaintiff may sue under RICO as a sovereign and as a "person." The term "person," within the RICO context is broad, encompassing "any individual or entity capable of holding a legal or beneficial interest in property." 18 U.S.C. § 1961(3). As argued in *Summit*, cities, counties, states, and governmental entities – like Plaintiff – have a legal and beneficial interest in multiple kinds of property that fall within the definition of commercial interests. *Wellborn v. Bank of N.Y. Mellon Corp.*, 557 F. App'x 383, 387 (5th Cir. 2014) (recognizing that a governmental entity may sue under RICO for injuries to commercial activity which were not satisfied when injury was to recording system that was "not created to serve a "revenue-generating function"); *City of New York v. Smokes-Sprites.com, Inc.*, 541 F.3d 425, 445 (2d Cir. 2008) (expressly rejecting dicta from *Town of W. Hartford v. Operation Rescue*, 915 F.2d 92, 103-04 (2d Cir. 1990), and holding that "lost taxes can constitute injury to 'business or property' for purposes of RICO . . . notwithstanding that [the City's] injury did not arise from its participation in a commercial transaction "), *rev'd on other grounds*, *Hemi Group, LLC v. City of N.Y.*, 559 U.S. 1 (2010); *Ill. Dep't of Revenue v. Phillips*, 771 F.2d 312, 314-16 (7th Cir. 1986). The Distributors have provided this

[64] Plaintiff incorporates and adopts the arguments regarding standing from the *Summit* Opposition at Section I.B.2.a.

Court with no authority for the proposition that the Plaintiff does not qualify as a person because it is a sovereign other than irrelevant cases analyzing FCA and § 1983 claims that have no application in the RICO context.[65] Furthermore, as discussed below, multiple courts have recognized that governmental entities are persons within the RICO context and upheld claims by those governmental entities for the kinds of damages that Plaintiff seeks. For their part, the Manufacturers cite multiple cases for the general proposition that Plaintiff cannot recover as a sovereign nation for generalized harm to its economy. Mfr. Mem. at 25-26. However, these cases are inapplicable because Plaintiff does not seek recovery for generalized harm to the economy or their ability to carry out governmental functions. The cases cited by the Manufacturer and Distributor Defendants are inapposite.[66]

Second, the RICO Defendants' argument ignores recent and relevant decisions, argued in *Summit County*, including *Wellborn*, 557 F. App'x at 387 (holding that plaintiff could not sue because the injury did not affect an interest that was "created to serve a revenue-generating function for the states."); *City of New York*, 541 F.3d at 445 (allowing city to sue under RICO for lost tax revenue); *Ill. Dep't of Revenue*, 771 F.2d at 314-16

[65] *Vermont Agency of Nat. Res. v. U.S. ex. rel. Stevens*, 529 U.S. 765, 766 (2000) (analyzing whether a state agency qualified as a person subject to *qui tam* liability under the FCA); *Inyo Cty., Cal. v Paiute Sho-Shone Indians of the Bishop Cmty. of the Bishop Colony*, 538 U.S. 701, 711-12 (2003) (determining that the Sho-Shone Tribe were not "citizen[s]" or "other person[s]" who could utilize § 1983 claims as a means for withholding evidence relevant to a criminal investigation).

[66] In *Canyon Cty. v. Syngenta Seeds, Inc.*, the plaintiff alleged no concrete financial loss caused by the alleged scheme and was not suing to abate a public nuisance (a recognized exception to the application of the municipal recovery rule which plaintiff conceded applied). 519 F.3d 969 (9th Cir. 2008). In *Cty. of Oakland v. City of Detroit*, the Sixth Circuit upheld Oakland's RICO claim against Detroit's challenge even where Oakland had arguably passed on its damages to consumers and was purportedly without an injury. 866 F.2d 839, 848-51 (6th Cir. 1989). The Court noted the importance of a "case by case" standing analysis "in deciding whether the law affords a remedy in specific circumstances," and recognized not only that recovery "would, presumably, redound to the benefit of the counties' residents" but also that the defendants had an alleged improper motive. *Id* at 850. Here, Plaintiff's damages include direct injuries to Plaintiff's revenue generating function resulting in unreplaced lost revenue and reduced tax income. FAC ¶¶ 852, 883.

(rejecting the notion that a government unit suing under RICO is limited to competitive or commercial injuries). Here, Plaintiff pleads the kinds of injuries to revenue-generating functions that were recognized in *Wellborn.*

Third, Plaintiff's lost tax revenue satisfies the requirement of an injury to business or property, and the Manufacturer and Distributor Defendants provide the Court with no cases holding otherwise. *See City of New York*, 541 F.3d at 445. The Manufacturers rely on *Town of W. Hartford*, despite the fact that it was "expressly rejected [as] dicta" by the Second Circuit,[67] and *Canyon County*,[68] which relies on *Town of W. Hartford*. The remainder of the Manufacturers' cases are no more persuasive. In *Arias v. DynCorp*, 752 F.3d 1011, 1015 (D.D.C. 2014), the plaintiff alleged that aerial spraying "caused health problems and [drove] large numbers of people away from the affected areas, which in turn forced the provinces to invest in additional schools, health centers, and other infrastructure along the border," and "allegedly cost [the plaintiff] tax revenue." But the plaintiff could not connect its alleged financial injuries and the defendants' spraying. *Id.* (holding that the plaintiff "failed to show that these injuries were 'fairly traceable' to the defendants' actions"). Here, unlike *Arias*, Plaintiff does more than merely allege that people left the area because of health problems. Rather, Plaintiff alleges that the opioid epidemic, created by the Manufacturer and Distributor Defendants, is killing citizens within Plaintiff's jurisdiction, driving down the cost of property, and decreasing business investment. There is a direct causal link between the RICO Defendant's actions and the

[67] *City of New York*, 541 F.3d at 445 ("We see no reason to import an additional standing requirement on municipalities for RICO claims, and thus expressly reject our dicta to the contrary in *Town of West Hartford.*"). The Second Circuit noted, in expressly rejecting *Town of West Hartford*, that the *Canyon County* decision relied on the dicta in *Town of West Hartford. Id.*

[68] 519 F.3d at 978-79.

injury to Plaintiff's revenue generating function – taxation. And, unlike *Cleveland v. U.S.*, 531 U.S. 12 (2016), the receipt of tax revenue is not something that "may" occur, it is a concrete reality that "must" occur. Therefore, neither *Arias* nor *Cleveland* require dismissal of Plaintiff's claims.

Finally, Plaintiff pleads categories of damages that are direct and not derivative of personal injuries. Plaintiff alleges that it was directly injured in its business and property by the opioid epidemic that was created by the Manufacturer Defendants' fraudulent marketing, and the Manufacturer and Distributor Defendants' failure to identify and report suspicious orders, all of which fostered and sustained the opioid epidemic—*i.e.*, the exact harm that the CSA was designed to prevent. FAC ¶¶ 850-03, 878-86, 880-87; *see also* H.R. Rep. 91-1444 (1970), *as reprinted in* U.S.C.C.A.N. 4566, 4571-72 ("[A] closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotics and dangerous drug control."); *United States v. Moore*, 423 U.S. 122, 135 (1975) ("Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.") (citations omitted).

On this point, again, the Manufacturer and Distributor Defendants copy their prior argument. But Plaintiff's damages arise directly, foreseeably, and traceably from Defendants' misrepresentations and omissions. FAC ¶¶ 852-53, 883, subparagraphs a, h-i, k-m.

The Distributor Defendants' reliance on the decisions in *Hawaii Health & Welfare Tr. Fund for Operating Engineers v. Philip Morris*, 52 F. Supp. 2d 1196 (D. Haw. 1999) and *Gucwa v. Lawley*, 731 F. App'x 408 (6th Cir 2018), are similarly unavailing. In *Hawaii Health* the plaintiff sought to recover for the increased cost of medical care and the court dismissed that claim, finding that it was too remote and founded, in all material respects, on personal injury to smokers. 52 F. Supp. 2d at 1200. And, in *Gucwa*, the court merely followed the logic of *Jackson* to dismiss RICO claims for lost workers' compensation. *Gucwa*, 731 F. App'x at 412 (citing *Jackson*, 731 F.3d at 566). Neither case warrants dismissal because, here, the Tribe pleaded direct injuries to its revenue generating function that are not derivative of personal injuries.

C. Plaintiff Pleads a Cognizable RICO Claim Pertaining to the Opioid Marketing Enterprise.

The Manufacturers raise no arguments for dismissal specific to Plaintiff's RICO claim pertaining from the Opioid Marketing Enterprise. Instead, they rely on their generalized arguments about proximate cause and pleading with particularity. To the extent that the Manufacturers also rely on their arguments from *Summit County*, Plaintiff incorporates Section I.B.3. of the *Summit* Opp. Mem. by reference.

D. Plaintiff Pleads a Cognizable RICO Claim Pertaining to the Opioid Supply Chain Enterprise.

1. The Distributor Defendants Controlled and Participated in the Opioid Supply Chain Enterprise.

The Distributor Defendants argue that Plaintiff's RICO Supply Chain claim must be dismissed because Plaintiff has not pleaded the existence of an enterprise or the RICO Distributor' participation therein. Distributors raise four arguments, all themes on prior

arguments that were addressed at length in the *Summit County* Omnibus Opposition. Each of these arguments fails as a matter of law.

First, the RICO Distributor Defendants argue that allegations of parallel profit-seeking activities are insufficient to establish a RICO enterprise. However, as argued in the *Summit* Opposition, the statement that parallel profit-seeking activities do not create a RICO enterprise is not true. Here, Plaintiff provided the context within which parallel activity may become evidence of a RICO enterprise. *Robins v. Global Fitness Holdings, LLC*, 838 F. Supp. 2d 631, 652 (N.D. Ohio 2012). And, Plaintiff alleges that the Distributors, at a minimum, refrained from competitive activities like reporting their competitors' suspicious orders and, incredibly, struck the exact same balance of identifying and reporting suspicious orders, including the decision to completely ignore their obligations. *See* FAC ¶¶ 799-803. These practices are anything but routine business relationships. Also ignored are the allegations that "suggest[] the agreement necessary" to demonstrate that the Distributor Defendants formed an association in fact enterprise and, at a minimum, participated in the conduct of that enterprise. *See* FAC ¶¶ 497-585, 799-803. These allegations demonstrate that the Distributors closely interacted in organizations that encouraged personal relationships, and used those organizations to form agreements about subjects like the duty to identify and report suspicious orders. FAC ¶¶ 530-32. Moreover, these allegations demonstrate that the organizations in which the Manufacturers and Distributors participated were actually used to form agreements on coordinated approaches to the issues in this case. *Id*.

Distributors also cite inapposite, out-of-Circuit cases that allegedly stand for the proposition that RICO enterprises are not formed by profit-seeking motives or

participation in trade associations. For example, in *American Dental Ass'n v. Cigna Corp*, the court clarified that "[it was] not convinced that Plaintiffs actually allege parallel conduct." 605 F.3d 1283, 1294 n.4 (11th Cir. 2010). Unlike *American Dental*, Plaintiff has alleged substantially identical conduct – the failure to identify, report and halt suspicious orders of controlled substances with examples of that conduct, ways in which participation in the PCF and HDA encouraged the formation of relationships among the members of the Opioid Supply Chain Enterprise and the ways in which the RICO Supply Defendants utilized their membership in those associations to further the interest of the Opioid Supply Chain Enterprise. *See* FAC ¶¶ 497-585, 530-32, 799-803.

Plaintiff alleges a common illicit purpose shared by all RICO Supply Chain Defendants that goes beyond merely making more money. *Ray v. Spirit Airlines, Inc.*, 836 F.3d 1340, 1352 (11th Cir. 2016) (holding that plaintiff did not allege facts to support a plausible inference that technology vendors participated or were involved in decisions about how to portray Spirit Airlines' fees). Furthermore, *Bible v. United Student Aid Funds, Inc.*, 799 F.3d 633, 656 (7th Cir. 2015), does not support Distributor Defendants' argument because there, like here, the plaintiff pleaded more than a run-of-the-mill commercial relationship. Here, Plaintiff alleges that each member of the Opioids Supply Chain Enterprise participated in the conduct of the enterprise by failing to identify, report and halt suspicious orders of controlled substances in order to increase and maintain artificially high quotas and thereby increase profits from the sale of a higher volume of opioids. FAC ¶¶ 474-585, 799-827. Plaintiff further alleges how this was more than merely parallel conduct with each RICO Supply Chain Defendant acting in its own self-interest. *Id*. Thus, as in *Bible*, the Plaintiff has stated a claim under RICO.

Second, the Distributor Defendants argue that Plaintiff fails to plead that they conducted or participated in the conduct of the Opioid Supply Chain Enterprise and failed to demonstrate that any of the Distributors made decisions on behalf of the enterprise. Plaintiff incorporates the law cited in the *Summit* Opp. Mem. at 55-59.

Here, Plaintiff alleges facts showing that each of the Distributor Defendants participated in making decisions about the formation and conduct of the Opioid Supply Chain Enterprise. FAC ¶¶ 513-35, 564-85. And the Distributor Defendants participated by carrying out the decisions of the Opioid Supply Chain Enterprise, including: refusing to report and reject suspicious orders of controlled substances (including their competitors' suspicious orders); publicly misrepresenting their compliance with the duty to identify and report suspicious orders; and applying for ever increasing quotas governing prescription opioids. FAC ¶¶ 476, 498-504, 513-38, 564-85, 799-803, 805, 806-07, 809. Unquestionably, the Distributor Defendants were aware of the Opioid Supply Chain Enterprise's common purpose, made decisions that conducted the enterprise, and participated in the conduct of the enterprise by implementing them.

2. Felony Violation of § 843(a)(4)(A) of the CSA is an Actionable Racketeering Activity Pursuant to RICO § 1961(1)(D).

Manufacturer and Distributor Defendants named in Plaintiff's Second Claim for Relief both argue, in identical fashion to their *Summit County* motions to dismiss and reply briefs, that violation of 21 U.S.C. § 843(a)(4)(A) is not a racketeering activity (either by incorporating their *Summit County* arguments or by re-arguing them). In addition to their older arguments, the Manufacturers raise the new argument that a felony violation of § 843(a)(4)(A) sounds in fraud and must, therefore, be pleaded with particularity. The Manufacturer and Distributor Defendants' arguments are no more

persuasive now than they were before. As discussed below, the new argument regarding particularity lacks merit.

1. In *Summit County*, the Manufacturers admitted that "certain conduct involving the manufacture and distribution of controlled substances may constitute a predicate act if it is "punishable by imprisonment for more than one year," but argued that the conduct alleged in Plaintiff's Complaint is not racketeering activity because failing to identify, report and halt suspicious orders is, at most, a violation of CSA § 842(a)(5) rather than a violation of CSA § 843(a)(4)(A). Here, as in *Summit County*, the argument is unpersuasive because Plaintiff pleaded a felony violation of the CSA that is punishable for more than one year, *i.e.* a violation of CSA § 843(a)(4)(A). *See Summit* Opp. Mem. at 59-64; FAC ¶¶ 864, 866.

2. The Manufacturers continue to argue that they do not have a duty to report downstream orders. However, the Manufacturers' argument, identical to that asserted in *Summit County*, ignores the fact that all registrants have a duty to prevent diversion by identifying and reporting suspicious orders. 21 U.S.C. § 823(a); 21 C.F.R. § 1301.74; *see also Summit* Opp. Mem. at 60-61. Here, again, the Manufacturers are attempting to limit their liability by reading words into the statute and regulations at issue. And, although they argued that Plaintiff failed to meaningfully respond to this argument in *Summit County*, there can be no more argument than the fact that the Manufacturers wholly fabricated their theory from language that is not included in the statute and regulations. Plaintiff therefore incorporates the arguments from the *Summit* Opposition. *See Summit* Opp. Mem. at 60-61. Without any new support for this argument, the Manufacturers' position is similarly unpersuasive when applied to this Plaintiff.

3. The Manufacturers continue to argue that they had no duty to stop shipment of suspicious orders. And, while the Manufacturers argued in their *Summit County* reply that Plaintiffs had not supplied any authority for a requirement to stop shipment, the authority cited in the *Summit* Opposition, and discussed in detail in *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212-13 (D.C. Cir. 2017), begs a contrary conclusion. *See Summit* Opp. Mem. at pp. 61-62; *see also Masters Pharm.*, 861 F.3d at 212-13 (citing 21 C.F.R. § 1301.74; *Southwood Pharm., Inc. Revocation of Registration*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007)). Here, the Manufacturers argue that *Masters Pharmaceutical* is inapplicable because it dealt only with distributors and that the DEA's interpretation of § 1301.74 is not entitled to *Chevron* deference because the "stop shipment" requirement was allegedly first introduced in the "Dear Registrant" letters issued by the DEA beginning in 2006. Both conclusions lack merit. Although *Masters Pharmaceutical* dealt with a registrant that happened to be a distributor, the regulations cited by the *Masters Pharmaceutical* court apply with equal force to manufacturers and distributors because they apply with equal force to all "registrants," including manufacturer registrants. The *Masters Pharmaceutical* court recognized that the "Shipping Requirement" "mandates that pharmaceutical companies exercise 'due diligence' before shipping any suspicious order. 72 Fed. Reg. at 36,500. DEA first articulated that requirement in *Southwood*, 72 Fed. Reg. at 36,501." *Masters Pharm.*, 861 F.3d at 221-22. Here, contrary to the Manufacturers' argument, the "Shipping Requirement" applies to all pharmaceutical companies and has been firmly entrenched as a part of the DEA's interpretation of the CSA and regulations since at least *Southwood*. Moreover, decisions like *Southwood*, the action against Mallinckrodt, and the "Dear

Registrant" letters are all DEA interpretations that are entitled to *Chevron* deference. *Summit* Opp. Mem. at 61-62.

4. The Manufacturer and Distributor Defendants argue that a felony violation of CSA § 843(a)(4)(A) does not satisfy the definition of racketeering activity in RICO § 1961(1)(D) because a violation of that provision is nothing more than a record-keeping violation. However, as explained at length in the *Summit County* Opposition, none of the RICO Defendants presented this Court with any authority for their interpretation of this newfound category of crimes (i.e. record-keeping felonies versus drug felonies), and their position is contradicted by the history of the CSA which specifically documents that the record keeping and reporting requirements in the CSA were designed to prevent the illegal diversion of controlled substances. Plaintiff incorporates the law and argument from the *Summit* Opposition. *See Summit* Opp. Mem. at 62-64.

5. The Distributors have previously argued that there is no private right of enforcement of the CSA. However, the Distributors have provided no new authority for that proposition.

6. The Manufacturers raise a new argument by attempting to place a felony violation of the § 843 of the CSA under the rubric of fraud and argue that felony violation of the CSA must be pleaded with particularity. Manufacturers have provided the Court with no authority for the proposition that a violation of § 843(a)(4)(A) sounds in fraud or that it needs to be pleaded with particularity, and the sufficiency of the pleadings under Rule 9(b) is independently well-established here. *See supra* Section II.D). Without more, this argument fails as a matter of law.

3. Distributor Defendants' Role in Setting Opioid Quotas Is a Proper Component of Plaintiff's RICO Claim.

Distributor Defendants argue that their role in setting opioid quotas cannot provide a basis for liability under RICO. The paragraphs cited by the Distributor Defendants discuss the ways in which RICO Manufacturer and Distributor Defendants surreptitiously attempted to avoid DEA enforcement, undermine the CSA, and misrepresent, through their Front Groups and trade associations, that they were complying with their obligations under the CSA. This is not protected lobbying activity.[69] And, the RICO Distributor Defendants' conclusion that failure to report suspicious orders cannot form the basis of RICO liability is unsupported by any relevant cases. To the contrary, *Ayres v. General Motors Corp.*, 234 F.3d 514, 521-25 (11th Cir. 2000), relied on by the RICO Distributor Defendants, supports a finding of mail and wire fraud for failure to report suspicious orders. As a preliminary matter, the Eleventh Circuit began its analysis in *Ayres* begins by acknowledging that "[a]mple case law supports [the] legal theory" that "nondisclosure of material information can constitute a violation of the mail and wire fraud statutes where a defendant had a duty to disclose." *Id*. at 521. Despite this authority, the *Ayres* court held that no mail or wire fraud occurred because the National Traffic and Motor Vehicle Safety Act, 49 U.S.C. § 30118 *et seq*. [hereinafter "Safety Act"], which was at issue in *Ayers*, maintains "its own extensive array of administrative remedies for violation of its notification obligations." 234 F.3d at 522. Unlike the CSA, the Safety Act allowed "any interested person" to "file a petition

[69] Moreover, the first two points raised in page 10 of the Distributor Defendants' brief are based on a misunderstanding of Plaintiff's allegations. The omissions and misrepresentations that form the basis of the mail and wire fraud claims are the failure to identify and report suspicious orders. Increased quotas and lobbying efforts are also actions that were taken as part of the overall scheme, but they are not the omissions and misrepresentations themselves.

with the Secretary of Transportation requesting the Secretary to begin a proceeding to decide whether to issue an order requiring a manufacturer to give notice" under the Safety Act. *Id*. "Furthermore, the Attorney General is authorized to bring a civil action to enforce the Safety Act and the notification obligations." *Id.* "A person found in violation of [the Safety Act]'s notification requirement in this civil action is liable to the United States Government for a civil penalty of not more than $1000 for each violation and not more than $800,000 for a related series of violations." *Id.* "Lastly, the Safety Act does not make violation of the notification requirements criminal." *Id*. These many differences distinguishing the Safety Act from the CSA, coupled with *Ayres*' acknowledgment that ample case law supports nondisclosure as a basis for mail and wire fraud, compel the conclusion that *Ayres*, to the degree it is apposite here, supports the Tribe's RICO pleadings.

V. CONCLUSION

The Blackfeet Tribe has adequately stated claims upon which relief can be granted. Defendants' dismissal demands misstate the operate substantive laws and fundamentally mistake the purpose of Rule 12(b)(6) by trying to shoehorn fact-based arguments into motions to dismiss on the pleadings. Defendants' motions to dismiss the Tribe's case, without consideration of the evidence of the calamity that Defendants' misconduct has caused, are unfounded. The Tribe prays that Defendants' motions be denied in their entirety.

Dated: September 28, 2018

Respectfully submitted:

BLACKFEET TRIBE OF THE BLACKFEET INDIAN RESERVATION, Plaintiff

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 28th day of September 2018, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF System. The foregoing will be served on counsel of record via the CM/ECF system.

/s/ Archie C. Lamb, Jr.
Archie C. Lamb, Jr.